HOSPITAL CHRONICLES 2006, SUPPLEMENT: 120–122

Challenges and Caveats for stents of New Technology: Which stent is better? What are the results in high – risk patients?

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Coronary stenting has revolutionized percutaneous coronary revascularization. Two landmark studies published in 1994, Benestent and STRESS, demonstrated the significantly superior outcomes of intracoronary stenting versus balloon angioplasty [1,2]. However, the success of bare–metal stents was limited by the occurrence of neointimal hyperplasia (NIH) leading to in–stent restenosis (ISR). The problem of neointimal hyperplasia, as measured by late loss, represented a significant hurdle, limiting the long-term patency of stents in many patient populations. The solution to the problem of ISR (the Achilles heel of the stent) was given by the evolution of new stent platforms coated with polymers eluting anti-proliferative drugs, drug eluting stents-DES.

The therapeutic objective of using a drug – eluting stent is to inhibit the excessive neointimal proliferation post – stenting that is responsible for late loss, leading to restenosis and an increased risk of reintervention. The original pivotal trials of the drug eluting stents SIRIUS (sirolimus – eluting stent) and TAXUS IV (paclitaxel – eluting stent) did indeed show significant reductions in restenosis and target lesion revascularization (TLR) rates compared to bare metal stents (Figures 1, 2) [3,4].

Thus, drug – eluting stents (DES) have been enthusiastically adopted by interventional cardiologists worldwide triggering an interest for the conduction of new studies assessing their performance in high – risk populations and in ever – more complex lesions. Patients with small vessels (<2-8 mm) [5,6], bifurcation lesions [7,8], long lesions [9,10], chronic total occlusions [11], diabetic patients [10,12], and patients with multivessel coronary artery disease have been randomized to comparative studies with BMS and have shown a remarkable reduction of TLR and in-stent binary restenosis.

These beneficiary results have increased the body of clinical evidence and broadened the spectrum of their indications and use in interventional cardiology even in patients with unprotected left main stem disease. In a recent study Valgimigli M et al concluded that when percutaneous intervention is undertaken at left main lesions, routine DES implantation reduces the cumulative incidence of myocardial infarction and the need of target vessel revascularization compared with the BMS [14].

Since March 2003 both DES Cypher (SES) (Cordis/J+J) and Taxus PES (Boston Scientific) have been commercially available worldwide. Both stent platforms elute anti–proliferative drugs with comparative reductions of TLR and binary restenosis in the aforementioned studies and it may appear reasonable to consider both DES to be equivalent on the basis of class effect. However, there are a number of significant differences in both stent platform and drug which make it far from certain that SES and PES are actually clinically equivalent.

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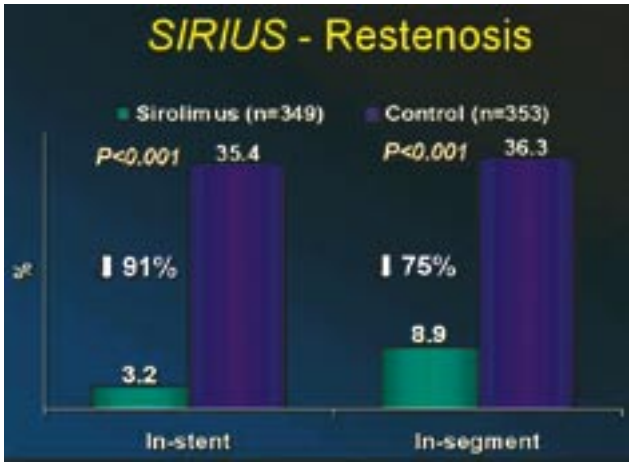

FIGURE 1. Results of the SIRIUS trial [3].

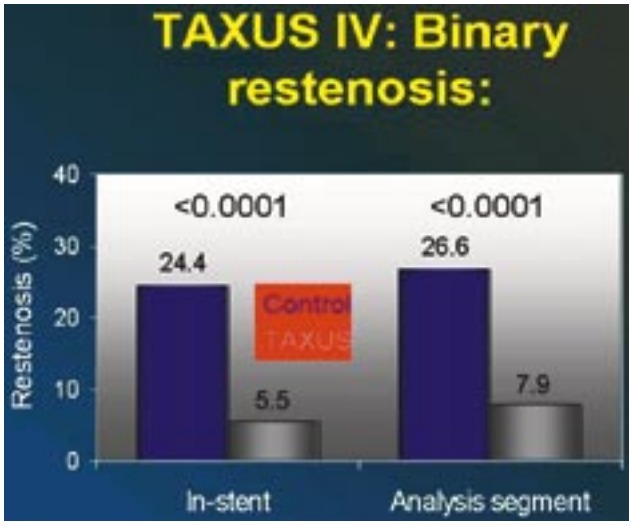

FIGURE 2. Results of the TAXUS trial [4].

More recently we have had the opportunity to compare the two commercially available DES following the presentation of data from head to head comparisons. In a meta–analysis study Kastrati et al concluded that SES-Cypher outperforms PES–Taxus in terms of clinical and angiographic restenoses rates [15]. However other studies do not confirm this superiority [16,17].

So the question "which stent is better"? is up to now difficult to answer so the issue it's rather rhetorical. It remains to be answered in the future.

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