SASCI Review and Recommendations

DRUG ELUTING BALLOONS (DEB) IN THE TREATMENT OF CORONARY ARTERY DISEASE

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INTRODUCTION

DEB have a number of advantages over standard angioplasty and stent technologies including (i) the potential for homogeneous drug delivery to the vessel wall which is not accomplished using DES, (ii) an immediate drug release without the use of a polymer which can induce chronic inflammation and late thrombosis as observed with some DES, (iii) the option of using balloon catheters alone or in combination with a bare metal stent, (iv) no foreign object such as DES left behind in the body, (v) the potential of reducing antiplatelet therapy, and (vi) lower restenosis rates in coronary arteries compared to conventional treatment. Thus, the concept of using a balloon catheter to directly deliver an anti-restenotic drug at the site of injury is of paramount interest and very convincing. The extension of endovascular therapy to longer and more demanding lesions might also increase the demand for a method that reduces the risk of restenosis without irreversibly modifying the structure of the vessel.

SCIENTIFIC EVIDENCE

The results from several randomised controlled coronary clinical trials consistently show that paclitaxel in a matrix of soluble additive coated on balloons reduces neointimal formation, as well as late lumen loss, restenosis, and repeat revascularisation in patients with complex coronary artery lesions. It seems that in the coronary circulation, paclitaxel coated balloon angioplasty holds the greatest promise for lesions in which stent deployment is not desirable or technically challenging (e.g., in-stent restenosis (ISR), long and distal lesions, very angulated segments, small vessels or bifurcation lesions).

So far, data from randomised clinical trials identify the treatment of coronary ISR [1, 2,] and of de novo and restenotic lesions in peripheral artery disease as viable options [3]. Drug eluting balloons have been shown to be better for the treatment of restenosis in both bare metal and drug eluting stents. [4]

Furthermore, results from first non-randomised series and clinical experience identify the treatment of de novo lesions in small coronary vessels [5], bifurcation lesions [6, 7] long lesions as potential beneficial indications for DEB catheters in the coronary arteries.

A recent real world registry in 479 patients using the Sequent Please drug eluting balloon in patients with small vessel disease was reported [8].

They showed a remarkable restenosis rate at 9 months of only 3, 6% as opposed to a restenosis rate of about 35% with bare metal stents and more than 10% with DES.

In the registry there was a 6% bail out with the DEB requiring stenting but this is offset by the low restenosis rate in the group of patients not requiring bail out.

SASCI RECOMMENDATIONS (also based on ESC recommendations [9])

Based on the current knowledge and scientific data available to us we would currently recommend the following

1. Drug eluting balloons (DEB) are the treatment of choice for the treatment of in stent restenosis both in bare metal and drug eluting stents. Class 2A indication in the 2010 ESC PCI guidelines.
2. It is very reasonable to use the DEB in the case of small coronary arteries (2mm-2.8mm). Restenosis rates in this group of patients with drug eluting stents are >10%.
3. It is very reasonable to use the DEB in the side branch when performing angioplasty in bifurcation lesions.
4. Patients on oral anticoagulation or at high risk for initiation of anticoagulation.
5. Patients with high bleeding risks or other need for reduced time of dual antiplatelet therapy.
6. Patients with former subacute stent thrombosis.
7. Patients with vasospastic angina

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