Drug-Eluting Balloon in ISR, Small Vessel, and Bifurcation Lesions

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Drug-Eluting Balloon (DEB) have many potential advantage; deliver drug over very short period of time, 100% lesion coverage, polymer and strut free, no additive multiple layer in in-stent restenosis (ISR) treatment, cross lesion easily. Paclitaxel fulfills the essential factors of ideal drug for DEB due to increased tissue residence times, most commercial available DEB are coated with 2~3 ㎍ paclitaxel / ㎟ balloon surface. Paclitaxel-eluting balloons can be divided into 2 groups, without Matrix & with Matrix. Matrix means paclitaxel is mixed with additives which can increase bio-availability of paclitaxel.

In BMS-ISR lesion, DEB showed very acceptable results of 6 month's late loss 0.1~0.2 mm, restenosis rate 5~8%, TLR 5~11 %, superior than paclitaxel-DES and plain old balloon angioplasty (POBA) by PACCOCATH and PEPCAD II long term follow up data. But in World Wide registry, MACE / TLR / TVR / MI rate was almost double in DES-ISR comparing BMS-ISR. For DES-ISR lesion, DEB is superior to POBA, similar with paclitaxel-DES in PEPCAD-DES and ISAR-DESIRE study. In recent RIBS IV randomized clinical trial for 309 patients of DES-ISR, everolimus-DES provided superior long-term clinical and angiographic results compared with DEB. So DEB angioplasty was more effective in BMS restenosis compared with DES restenosis. We need larger data to confirm 2nd generation DES is better than DEB or not in DES-ISR treatment.

In small vessel disease (smaller than 2.8 mm), late loss and binary restenosis rate was significantly low in DEB compared with POBA in PEPCAD I trial. But bailout BMS stent after DEB angioplasty showed relatively high late loss & restenosis rate. In recent BELLO trial treatment of small-vessel disease with a paclitaxel DEB was associated with less angiographic late loss and similar rates of restenosis and revascularization as a paclitaxel-DES. In not small De Novo lesion predilation with DEB before BMS implantation was inferior to implantation of an everolimus-DES in 9-month revascularization.

In bifurcated lesion, several trials focused on DEB angioplasty for side branch ostial lesion. In recent BABILON trial evaluated main branch BMS implantation after DEB of both main and side branch vs. provisional everolimus-DES implantation. MACE and TLR were higher in the DEB group due to higher main branch restenosis, no angiographic differences on late lumen loss of SB ostium after POBA or pDEB. Everolimus-DES present as a superior strategy in main branch and no advantage of using DEB in the side branch.

In summary, single-dose delivery of paclitaxel-matrix coating balloon is feasible and achieves therapeutic intra-vessel levels. In ISR, DEB angioplasty was more effective in BMS restenosis compared with DES restenosis. In small vessel disease, late loss and binary restenosis rate was significantly low in DEB only and addition of BMS to be avoided. No advantage of using DEB for side branch in bifurcated lesion