# Drug-eluting balloons: an update from their use in the peripheral and coronary field

The last few decades have witnessed considerable advances in intravascular interventions for the treatment of coronary and peripheral arterial disease, including the recent introduction of drug-eluting balloons (DEB). Data presented at the Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium and American Heart Association (AHA) Scientific Sessions in November of last year add to the growing body of evidence that DEB show promise as a viable alternative to standalone balloon angioplasty and stent implantation for the treatment of coronary and peripheral arterial disease.

At the TCT scientific symposium, Professor Bruno Scheller (University Hospital, Saarland, Germany) reported 6-month results from the IN.PACT clinical trial programme and specifically from the IN.PACT CORO ISR trial, as well as providing an overview of the FreePac (Medtronic, Inc.) technology. The IN.PACT programme includes 15 trials and more than 2,000 patients and will assess the efficacy and safety of the IN.PACT devices (Medtronic, Inc.), which include one DEB for use in the coronary setting (Falcon) and three devices for use in the peripheral setting (Admiral, Amphirion and Pacific). In his overview of the programme, Professor Scheller discussed the ongoing European IN.PACT SFA (superficial femoral artery) I trial, which compares the IN.PACT Admiral DEB with standard balloon angioplasty for treatment of *de novo* and restenotic lesions in the superficial femoral and proximal popliteal arteries.[1] He also reviewed final data from the IN.PACT CORO ISR trial that is evaluating the IN.PACT Falcon DEB as a treatment for coronary in-stent restenosis. At 6 months, in-stent late lumen loss was 0.07 mm, suggesting minimal tissue growth inside treated vessels.[1]

Results from The Balloon Elution and Late Loss Optimization (BELLO) study were recently reported at the 2012 Joint Intervention Meeting, Rome, Italy. This assessed late lumen loss at six months in the small coronary vessels in 182 patients randomized to IN.PACT Falcon DEB or the Taxus stent (Boston Scientific). The IN.PACT Falcon DEB was shown to be significantly superior to the Taxus stent in preventing late lumen loss (P=0.001) however, major adverse cardiac events rates were similar between the two interventions in small vessels. The BELLO data suggest a new indication for DEB not only for in-stent restenosis but also for *de novo* disease of small coronary arteries.[2]

Positive 1-year outcomes with DEBs were also reported in two abstracts at the TCT conference: one study in patients with femoropopliteal arterial disease using IN.PACT Admiral[3] and the other in patients with diabetes with critical limb ischaemia in below-the-knee vessels using IN.PACT Amphirion.[4] Other recently published data showed that the early restenosis rate of long-segment infrapopliteal disease is significantly lower after treatment with IN.PACT Amphirion compared with historical data using uncoated balloons.[5]

Two reports from the 2011 AHA Scientific Sessions support the use of DEB as a promising tool for the treatment of in-stent restenosis.[6, 7] Zadura et al. retrospectively investigated the responses of 84 in-stent restenosis patients who underwent revascularization using SeQuent Please paclitaxel-eluting balloons (B Braun). After 6–9 months, 85/91 (93.4%) lesions showed no significant loss of gain. Repeat in-stent restenosis (>50% of vessel lumen) occurred in 6/91 lesions (6.6%) with only three patients with 70% and 80% in-stent restenoses requiring an additional procedure.[6] In another study, the same research group followed 63 patients with *de novo* lesions being treated with paclitaxel DEB (Taxol, BMS; SeQuent Please) instead of a drug-eluting stent. After 6–9 months, 94.5% of patients experienced no significant restenosis. Four lesions showed repeated narrowing; however, only two patients required a subsequent targeted revascularization.[7] Since patients receiving a DEB require a shorter anticoagulation period versus drug-eluting stents (4 weeks versus 1 year of dual antiplatelet therapy), these findings suggest that DEB may provide an attractive alternative to stents for patients with a high risk of bleeding complications, as well as in elderly or non-compliant patients.

Recently, Gutiérrez-Chico and colleagues have shown that sequential application of a DEB and a non-pre-mounted bare metal stent (BMS) for treatment of *de novo* coronary lesions results in efficient inhibition of neointimal hyperplasia.[8] However, they reported that the order of application (DEB vs BMS first) had little influence

on neointimal hyperplasia, except that better stent apposition was observed in patients treated with BMS first.[8]

Following its initial development and publication of two landmark trials,[9, 10] numerous DEB technologies have been explored by various companies. Within the peripheral vasculature, DEBs are being evaluated for treatment of disease in the superficial femoral, popliteal and tibial-peroneal arteries. For coronary interventions, because DEB treat the artery without leaving a permanent implant, they provide an attractive treatment option for treating in-stent restenosis, bifurcation lesions and small arteries. The increasing availability of data with DEB support the current opinion that this novel therapeutic strategy is a viable alternative to standalone balloon angioplasty and stent implantation for the treatment of coronary and peripheral arterial disease. Further data are now required to establish the most appropriate role for DEB in the treatment of the numerous clinical problems managed by vascular interventions.


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