

# Role of Drug Eluting Balloons in Peripheral Endovascular Procedures

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## Abstract

In the last year's drug eluting technology (balloons and stents) moved from coronary to peripheral arteries. Manufacturers supported the evolution of these devices. Actually, Drug Eluting Balloons (DEBs) are widely used to treat all the peripheral arteries. The results are heterogeneous for each arterial bed analysed.

**Keywords:** Drug eluting balloon; Peripheral arteries; Endovascular procedures

## Background

In the coronary arteries Drug-Eluting Balloons (DEBs) have emerged as an exciting technology developed to overcome the limitations faced by drug-eluting stents, such as stent thrombosis and dependency on prolonged dual antiplatelet therapy, and may prove efficacious in complex subsets such as small vessels and diffuse lesions [1]. In particular, DEBs are commonly used in the coronary arteries to prevent restenosis, to treat in-stent restenosis, to treat small vessels, and to treat vessels where stent results are suboptimal [2].

In the last year's drug eluting technology (balloons and stents) moved from coronary to peripheral arteries. Manufacturers supported the evolution of these devices. Eight randomized controlled trials have been already published about the use of DEBs in femoro-popliteal and below-the-knee arteries. About ten clinical trials are still ongoing (supported by three different manufacturers).

So, actually DEBs are widely used to treat all the peripheral arteries. The results are heterogeneous for each arterial bed analyzed.

## Carotid Arteries

In 2012 two papers have been published about the use of DEBs in carotid arteries. Liistro *et al.* [3] reported two cases of treatment of a carotid in-stent restenosis with DEBs, and Montorsi *et al.* [4] described the same treatment in seven patients; the acute and midterm results seem to be encouraging.

So, the use of DEBs in carotid arteries is anecdotal. This use is an off-label use of these devices. No any other paper has been published during 2013.

## Aorta and Iliac Arteries

No paper has been published in literature about the use of DEBs in aorta or iliac arteries.

In our center we used DEBs to treat 3 cases of iliac in-stent restenosis. At a mean follow-up of 15 months the primary patency and the absence of significant restenosis is 100%. These results are unpublished and the use of these devices in this arterial bed should be considered as off-label.

## Femoro-Popliteal Arteries

The use of DEBs in femoro-popliteal arteries is in indications for use. In some countries in Europe (such as Germany) there is an appropriate reimbursement situation for DEBs that covers their additional costs. The results of DEBs in femoro-popliteal arteries have been well established with randomized clinical trials.

In PACIFIER trial the authors randomized 85 patients in 3 different hospitals (44 to DEBs and 47 to uncoated balloons); they concluded that use of DEBs is associated with significant reductions in late lumen loss and restenoses at 6 months, and reinterventions after femoro-popliteal Percutaneous Transluminal Angioplasty (PTA) up to 1 year of follow-up [5].

In DEBELLUM trial the authors enrolled and randomized to DEB or standard PTA 50 consecutive patients with 122 lesions of the femoro-popliteal and/or below-the-knee arteries; this trial confirmed the ability of DEBs to reduce restenosis vs. conventional balloons at 6 months after treatment of multilevel disease [6]. One-year results confirm and reinforce initial 6-month outcomes [7].

In DEBATE-SFA trial 104 patients were randomly assigned to either DEBs + bare metal stenting or PTA + bare metal stenting; the authors concluded that pre-dilation with DEBs prior to stenting, as compared to PTA + stenting in femoro-popliteal lesions, reduces restenosis and target lesion revascularization at 1 year [8].

## Below-The-Knee Arteries

The use of DEBs in below-the-knee arteries is in indications for use.

In literature there is one randomized clinical trial. In DEBATE-BTK trial the authors enrolled and randomized 132 patients with 158 infra popliteal atherosclerotic lesions; they concluded that DEBs compared with standard PTA strikingly reduce 1-year restenosis, target lesion revascularization, and target vessel occlusion in the treatment of below-the-knee lesions in diabetic patients with critical limb ischemia [9].

However, recently a manufacturer stopped a post-marketing, multicentre, randomized controlled trial of below-the-knee revascularization in patients with critical limb ischemia because of the higher rate of major amputations in the patient's undergone DEB treatment. Furthermore, the manufacturer decided to voluntarily worldwide recall and stop selling of the specific DEB commercialized for the below-the-knee arteries.

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## Haemodialysis Arteriovenous Fistulas

No paper has been already published in literature about the use of DEBs in haemodialysis arteriovenous fistulas.

In our center in case of thrombosed prosthetic arteriovenous graft we usually performed a hybrid simultaneous treatment with surgical thrombectomy and endovascular treatment of the venous outflow stenosis. In 15 cases we performed a PTA with DEB. At a mean follow-up of 6 months the primary patency was 80%, and the use of DEBs significantly improved the 1-year primary patency respect to the stent placement (80% vs. 25%,  $p=0.02$ ).

In another Italian center the use of drug-eluting balloons, after standard angioplasty, improves primary patency and decreases reinterventions of target lesions in juxta-anastomotic stenoses of failing native dialytic arteriovenous shunts.

These studies have been already accepted for publication; however, the use of these devices in this district should be considered as off-label [10,11].

## Conclusions

The off-label use in carotid and aorto-iliac arteries is anedoctal and cannot be judged. The use in femoro-popliteal arteries has been well studied and the results are encouraging. The use in below-the-knee arteries should be stopped awaiting further analyses. The off-label use in hemodialysis fistulas is promising, but it should be better investigated.

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