



## EDITORIAL COMMENT

# Drug-eluting balloons: The path is made by walking<sup>☆</sup>

## Balão eluidor de fármaco: o caminho faz-se caminhando

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The concept behind drug-eluting balloons (DEB) is local vascular release of an antiproliferative drug without the need for a metal structure or a polymer, which is certainly an attractive idea and an important innovation in interventional cardiology.

Their use in the treatment of coronary artery disease is relatively recent, but DEB angioplasty has grown rapidly, in fact outstripping the evidence in this area. The history of interventional cardiology is full of such examples of action ahead of large trials and the guidelines based on them.

The development of this alternative was prompted by the fact that the use of stents is not advisable in certain situations or is likely to achieve less favorable results.

DEB angioplasty has been shown to be most useful for the treatment of in-stent restenosis, bifurcations and small vessel disease, particularly in patients with diabetes. All these situations are a challenge for interventional cardiology for which there is as yet no standard treatment, unlike conventional lesions for which stenting has become universally accepted.

A return to simple balloon angioplasty but with DEBs to reduce the risk of restenosis appears to be a path worth exploring and for which it is important to gather more evidence.

The multicenter series presented in the article by Calé et al. in this issue of the *Journal* provides interesting information on the use of DEBs, particularly in patients with small vessel disease, on whom there have been few large-scale studies.

Based on a prospective registry from two centers, the authors analyzed 156 consecutive patients in whom 184 lesions were treated, with a 12-month follow-up. The indications for DEB angioplasty were divided between in-stent restenosis and small vessel disease. The study analyzed major adverse cardiac events (MACE), including all-cause death, myocardial infarction (MI) and need for target lesion revascularization (TLR).

One important result was 98% device success, confirming the excellent navigability of the system, even in small vessels, in most cases with distal lesions.

The apparently high rate of MACE, particularly at 30 days, with two cardiovascular deaths, four MI and two TLR, may be explained by the population studied, which included a higher than usual percentage of diabetic patients, and most of whom had significant coronary disease previously treated by angioplasty or bypass surgery.

It could be questioned whether analysis of clinical events is the best method to evaluate DEB angioplasty outcomes, since the rate of restenosis and need for TLR are of greater interest.

Clinical manifestations are not always typical in patients with in-stent restenosis or in diabetic patients with small vessel disease, as formation of collateral circulation is frequent in the former due to the gradual process of restenosis, and the percentage of patients with silent ischemia is high among the latter.

It would be interesting to see more studies on DEB angioplasty with angiographic assessment so as to obtain a better idea of its true efficacy. While there is an appreciable amount of evidence on its use for the treatment of in-stent restenosis,<sup>1,2</sup> an indication that is included in the latest European Society of Cardiology guidelines on myocardial revascularization, the results of studies on treatment

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of small vessel disease have been controversial or even negative.<sup>3</sup>

Although the study by Calé et al. found no significant difference in the occurrence of MACE between patients being treated for in-stent restenosis and those for small vessel disease, it is difficult to draw any conclusion as to whether DEB angioplasty was equally effective since the two situations are completely different.

One aspect that could have benefited from more detailed analysis was treatment of small vessel disease, since there have been few studies on this patient group, in whom balloon angioplasty is sometimes the only option. The definition of "small vessel" is not the same in all studies. The article states that the median DEB diameter was 2.5 mm, but it would be relevant to know the caliber of vessels in this group, particularly the proportion of patients with vessels of  $\leq 2$  mm, which present more of a challenge.

However, the study has the merit of pointing out other facts, including that the best predictors of vascular events are patient characteristics rather than the type of balloon employed or its length.

For all these reasons, the publication of registries such as this one is to be commended, especially in areas where information is sparse and off-label use is common in clinical practice.

While DEB angioplasty is beginning to gain wider acceptance for the treatment of in-stent restenosis, there is still

little information on the actual results of the technique in cases of small vessel lesions, particularly when diffuse.

A final word on the path chosen by the authors, which seems likely to bring benefits; sharing information, establishing multicenter registries, and developing joint projects is without doubt the best way to obtain results and to raise the profile of Portuguese interventional cardiology.

### Conflicts of interest

The author has no conflicts of interest to declare.

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