

Direct Stenting: The Decline of the Balloon?

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*The easier it is to do, the more difficult
it will be to change*
(The Eng Principle of medical procedures).

The article of Íñigo Lozano et al¹ in this issue is interesting inasmuch as it analyzes the experience of a single center with a large number of patients treated using the direct stenting technique, that is, stent implantation without previously conditioning the lesion by means of balloon dilatation or atherectomy. In recent years, the use of direct stenting has paralleled growth in the use of stents (which has become an omnipresent device in percutaneous coronary revascularization). The frequency of this procedure increased in Spain by 131% between 1999 and 2000.² This fact is reflected in the reference study, where direct stenting was 11% of stenting procedures in 1998, 26% in 1999, 37% in 2000 and 38% in 2001. The growth in the popularity of this technique is cause for reflecting on its safety and the immediate and long-term results compared with the traditional implantation technique with predilatation.

In first place, the high percentage of effective direct implants, which was similar in all the series published in recent years, must be interpreted in the light of the selection of the lesions to be treated. Lozano et al¹ noted that «the selection entailed in prospective studies does not always correspond with *routine practice*».¹ Nevertheless, retrospective studies are also selective, not in protocol but in *the criterion of the operator*, which reflects the *routine practice* of a group in which, logically, different criteria and degrees of experience coexist. This fact is evident from the fact that the anatomy of the lesions treated in a restrictive study, like DISCO,³ is similar to that included in the reference study, indicating that the operator acts in accordance with awareness of the apparent limitations of the technique, which coincide with those cited in the protocol as exclusion criteria. Ultimately, neither retrospective selection nor restricted prospective selection allows an

important question to be answered unequivocally: what anatomic circumstances allow direct stenting with a high degree of safety and what circumstance are predictive of a greater risk of failure or complication?

The analysis of the authors indicates the causes that, in their experience with 1000 lesions, reduce the probability of implant success: *a)* the degree of severity of the stenosis; *b)* tortuosity and calcification; *c)* angle of the lesion, and *d)* its location in the circumflex artery. Although these circumstances may be shared by most interventionist cardiologists, it is necessary to consider that *the current systems allow lesions to be treated that once were considered contraindicated for direct stenting less restrictively*. The sixth-generation stents now in use allow stent implantation to be attempted in most cases, and the carrier catheter can be removed without risk of stent loss or deformation in the case of access failure, unlike older systems in which stents are occasionally lost.^{1,4} Given the possibilities of the procedure, the reliable identification of less suitable injuries requires the consecutive treatment of all lesions or, at least, a very broad spectrum of lesions. This need moved the DISCO Group to plan a multicenter study, which recently concluded but has not yet been published (DISCO Study 2). In this study an attempt was made to treat by direct stenting all lesions eligible for treatment by percutaneous revascularization in seven hospitals (607 lesions altogether), with few exceptions, and to define the degree of tortuosity and calcification using objective criteria. In contrast to the percentages reported until now – 38% in 2001 in the study by Lozano et al¹ and 38.9% in the Registry of the Section of Hemodynamics of 2000² – 55% of all injuries treated with stent implantation were approached directly, which was equivalent to 46.1% of all PTCA procedures. The rate of primary success was 94.6% and secondary success (need for predilatation after removing the system), 5.1%. These data indicate that direct stent implantation can be successfully performed with safety in practically half of the lesions treated percutaneously and in more than 50% of the lesions treated by scheduled stent implantation. The segment of the population with chronic complete occlusion, aorto-ostial lesion, important calcification or tortuosity, or bifurcation with a large lateral branch, the patients excluded from DISCO 2, re-

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mains unexplored. Even so, these figures already come close to the world of real daily practice.

As regards the immediate results of direct stenting, it is noteworthy that earlier observations showing a similar degree of angiographic expansion in comparison with stenting with predilatation³ are confirmed in the study of Lozano et al.¹ The same conclusion has been reached using IVUS.⁵ The intrahospital clinical evolution (mortality, acute thrombosis, and other adverse episodes) did not differ from that reported in other published series, although here the reference study selected only patients treated for a single lesion. Unanimously, the cumulative experience of multiple controlled or observational studies^{3,6,7} showed no significant differences during follow-up for up to 12 months in terms of mortality, nonfatal AMI, or need for a new revascularization in populations randomized to stenting directly or after balloon dilatation.

Once its large-scale applicability, safety, and good immediate, mid-term and long-term results have been demonstrated, we must answer the question: *what is the advantage of direct stenting?* The response, according to some observational studies, is that this strategy reduces the duration of the procedure, exposure to radiation, volume of contrast, and amount of disposable material used (mainly balloon catheters). The DISCO and other randomized studies^{3,8} confirm these points and their positive influence on procedure costs, equivalent to a mean of about 1000 €. The phrase used as the title of a recent editorial commentary by Colombo:⁹ *Direct stenting: safe with advantages for the patient and for the doctor* could be expanded to include: *and for the nurse and manager*.

Unfortunately the available data do not allow it to be concluded that direct stenting reduces the incidence of restenosis, although this possibility had been shown in an animal model that showed a notable reduction in the degree of neointimal hyperplasia when stents were implanted without predilatation.¹⁰

None of the studies that have examined either angiographic restenosis³ or the percentage revascularization at 6 months¹¹ of lesions treated by direct stenting in humans have managed to demonstrate significant differences between the two implantation techniques. It is possible that in the near future the search for a solution to the problem of restenosis will conclude with the use of pharmacologically active stents. Nevertheless, the reduction of trauma to the arterial wall by eliminating predilatation may also offer advantages in relation to the immediate result of the procedure. The number of dissections associated with stent implantation tended to decrease with the direct technique. This avoids the need for implant one or more additional stents and could also reduce the incidence of acute thrombotic occlusion.³ Finally, an interesting possibility of direct stenting in the field of acute coronary syndrome, primary stenting in AMI, has not been explored completely, although preliminary results seem to indicate ad-

vantages insofar as the immediate restoration of a more adequate distal flow.¹² In these situations, in which the struggle against the thrombus is primordial, reducing intra-arterial manipulation could be advantageous in terms of preventing distal fragmentation and embolization and their harmful effects on the re-establishment of an optimal degree of reperfusion. This hypothesis must be confirmed in the short term, perhaps in conjunction with the systematic use of GP IIb/IIIa inhibitors.

In conclusion, a notable unanimity exists among published studies with regard to the immediate and long-term results of direct stenting, as well as its advantages. All this, together with the greater reliability of the stents themselves and the carrier systems has considerably increased the number of lesions where it can be used with extreme reliability. Other areas of investigation are open and it can be expected that the use of this technique will extend in the near future. The decline of the balloon is a reality.

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