EDITORIAL COMMENT

Directional Coronary Atherectomy and Implantation of Drug-Eluting Stents in Selected Bifurcation Lesions

A Logical Combination Waiting Evidence*

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Plaque removal with directional coronary atherectomy (DCA) and stent implantation appears to be a very rational binomial because a stent implanted on a lesion with a lower plaque burden should expand to a larger lumen area (1). A larger final lumen has always been a major requirement for most interventional coronary procedures. Unfortunately, when this logic was tested in the AMIGO (Atherectomy before Multi-link Improves lumen Gain and clinical Outcomes) trial, a dedicated, randomized trial comparing bare-metal stenting versus DCA before stenting, the results were quite discouraging (2). I always commented on the failure of the AMIGO trial with the statement, “atherectomy does not work according to the intention-to-treat principle.” The results of DCA in the AMIGO trial were quite suboptimal. Most of the lesions were left, with more than 60% of plaque burden, and this fact is, in my opinion, the main reason for such a failure.

The advent of drug-eluting stents (DES) giving minimal late loss (3,4) made the need to further optimize stent implantation, beyond a full apposition and reasonable residual lumen, an unnecessary objective. However, when DES started to be used in more complex lesions such as bifurcations, restenosis and the need for new revascularization became more frequent (5). The PERFECT (PrE Rapamycin-eluting stent FlExi-CuT) registry led by Takahiko Susuki and published in the current issue of the Journal (6) is a serious attempt to improve this area.

The first item to point out is that this study is a registry of selected lesions considered suitable for DCA. I like to state that this fact is not a real limitation but an appropriate way to start: a device or procedure should be used where it fits the best.

There are several important features about the PERFECT study that need to be highlighted:

- Atherectomy should only be used in situations where the operator expects a good result and low complications. To satisfy this goal, the interventionist needs to be selective. There is no question about the selectivity used in the PERFECT registry: the enrollment of 99 patients in 17 centers in 14 months testifies to this impression.
- All patients underwent intravascular ultrasound-guided DCA. This decision confirms that there was an attempt to obtain the best possible result aiming for a residual plaque burden of <60%. This goal was effectively reached with an average final plaque burden of 55.8% at the end of DCA. It is interesting that the authors comment on this result, stating: “debulking was not so aggressive.” As a comparison, the residual plaque burden in OARS (Optimal Atherectomy Restenosis Study), one of the most aggressive investigations with DCA conducted in the U.S., was 58% (7). Only the SOLD (Stenting After Optimal Lesions Debulking) registry and ABACAS (Adjunctive Balloon Angioplasty After Coronary Atherectomy Study) achieved better DCA results, with a final plaque burden of 49% and 45.5%, respectively (1,8).
- The primary end point of the study was binary restenosis. The decision to adopt this end point is very laudable because it is the only way to truly evaluate the performance of a technique or a device in bifurcation lesions where restenosis in the side branch may be clinically silent.
- Eighty-one percent of the lesions were located in the left main or at the ostium of the left anterior descending or of the circumflex. This decision is a very important selection criterion to improve effectiveness, safety, and cost benefit of a more complex and expensive approach.
- Atherectomy was performed mainly in the main branch, with only 3 lesions treated in the side branch as well. This information confirms that most of the plaques were confined to the main branch.
- No complications occurred during the procedure. This fact highlights the value of well-trained operators.
- In 97 lesions only 1 stent was needed, and in 2 lesions, 2 stents were implanted. To us, this fact highlights the selection performed by the operators to exclude lesions with disease extending toward the side branch. It is clear that plaque removal in the main branch may lower the risk of plaque shifting from the main branch toward the side branch. Nevertheless, we cannot understand how a

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procedure performed only on the main branch may positively affect the lesion of the side branch if such a lesion is more than a focal ostial narrowing. This consideration is supported by the fact that the average lesion length in the side branch was 7.1 mm.

- The use of an intra-aortic balloon pump was needed only in 11% of patients. Considering that 82% of the lesions were located around the left main bifurcation, these data further testify to the high skills and confidence of the operators.

Following these initial considerations, we now come to the main results:

- The procedural complications were surprisingly low, with only a 2% incidence of non–Q-wave myocardial infarction. These data can be accepted only when taking into account that short lesions were treated in this registry.
- The primary end point, binary restenosis, occurred in 1 lesion on the main branch and in 3 lesions in the side branch for a total restenosis rate of 4.5% (90% angiographic follow-up). In the 63 patients with lesions located in the left main trunk, there were no cases of angiographic restenosis.
- At 1 year follow-up, obtained in 97% of patients, there were no deaths and no myocardial infarctions, and 2 patients required a repeat percutaneous intervention. Dual antiplatelet therapy was prescribed to all patients for 1 year. No adverse events occurred in the 63 patients with lesions located in the left main trunk.

The most important learning and practice points we can extract from this study are:

1. The excellent results,
2. The need to be selective in deciding which lesion can be treated with such an approach, and
3. The need to master the skills of DCA.

The lesion selection is to us the most important area to elaborate. It is important to understand that a “complex lesion” encompasses a variety of categories: one item is a true bifurcation with the stenosis in the main branch 10 mm long and the one in the side branch 5 mm long, and another item is a lesion where the 2 branches have a stenosis of length 20 mm or more. Unfortunately, both lesions will be called “complex lesions.”

The key elements of the PERFECT registry are the statement “suitable morphology for DCA catheter delivery” and the information included in Table 3 describing the quantitative coronary angiographic characteristics of the lesions included. These features define the boundaries regarding the possibility to generalize these results to the world of complex bifurcations.

We are very pleased to see these outstanding outcomes because we know that when a bifurcation lesion satisfies practice point 2 and DCA is performed by an operator as described in practice point 3, we can achieve such superb results. Unfortunately, over this success hover a few uncertainties about the appropriate duration of dual antiplatelet therapy and the possible interaction between plaque removal and late stent malapposition. Only an extended follow-up and a larger number of patients may help to answer to these questions.

What is missing? We need to know the results we can expect when lesions similar to the ones included in the PERFECT registry are treated with a rapamycin-eluting stent without prior DCA.

What we should refrain from doing is trying to compare the results of the PERFECT registry with published data regarding bifurcation lesions unless we specifically know how many of them were suitable for DCA and how many lesions could fit within the standard deviations of the angiographic characteristics presented in Table 3 of the PERFECT registry.

The final logical conclusion is: let us set specific inclusion and exclusion criteria and consider a randomized trial. Maybe a pilot study only for left main lesions!

A risk is that the “Master DCA Operators” may become reluctant to randomize when they are confident about their current strategy (DCA before stenting), and we will be left with the skeptical and possibly “imperfect DCA operators” enrolling patients in the trial.

I sense that we are facing another question without a clear answer.

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REFERENCES