Directional coronary atherectomy in 2005

Alessandra Repetto, Marco Ferlini, Maurizio Ferrario, Luigi Angoli, Ezio Bramucci

Division of Cardiology, IRCCS Policlinico San Matteo, Pavia, Italy

Key words:
Coronary stenosis; Coronary stent; Directional atherectomy; Restenosis.

The original aim of atherectomy was to reduce restenosis by means of aggressive plaque debulking, and the failure of large randomized trials to show any advantage of atherectomy over balloon angioplasty restricted its wider application. However, single-center registries in which aggressive debulking was performed by experienced operators have reported favorable results in terms of reduced restenosis and improved clinical outcomes when atherectomy was performed before stenting. Plaque debulking reduces the potential for plaque shift and facilitates subsequent high-pressure stent expansion, smoothes the internal vessel surface, scaffolds intimal flaps, and prevents elastic recoil. It has also been demonstrated that atherectomy can play a role in the treatment of complex lesions (ostial left anterior descending coronary artery lesions, left main lesions, and bifurcations), in which plaque shift may compromise the result of the procedure.

New-generation devices have shown that atherectomy can be safely and effectively used to treat even relatively small vessels.

In the current era of drug-eluting stents characterized by a considerable reduction in restenosis rates, optimal stent geometry and final luminal diameter are still important predictors of restenosis. Given the possible role of plaque shifting at the edges of a stent in causing restenosis, debulking could be added to the local drug effect in complex lesions.

(Ital Heart J 2005; 6 (6): 494-497)

Address:

Dr. Ezio Bramucci

Divisione di Cardiologia
IRCCS Policlinico
San Matteo
Piazzale Golgi, 2
27100 Pavia
E-mail:
laboratorio.emodinamica@smatteo.pv.it

Coronary restenosis is still the main limitation of percutaneous coronary interventions. The use of stents in more than 80% of procedures has reduced the incidence of restenosis, but created a "new enemy that is more difficult to treat": the in-stent restenosis underlying the failure of about 20% of successful procedures using bare metal stents.

Restenosis after percutaneous transluminal coronary angioplasty (PTCA) is the result of interactions between elastic recoil, neointimal proliferation and vascular remodeling whereas, after stent implantation, restenosis is mainly caused by smooth and fibrotic cell hyperplasia.

Post-PTCA residual plaque is considered as being a major determinant of restenosis risk: the inverse relationship between final minimal luminal diameter and restenosis has been well documented, and is reported in the English literature as the "bigger is better effect"[1], whereas "less is better" has been demonstrated to be the rule when talking about final plaque volume in relation to restenosis[2].

These observations have encouraged the introduction of a more aggressive revascularization technique whose specific aim is to "debulk" as much plaque as possible in order to obtain a larger final luminal diameter.

Directional coronary atherectomy (DCA) was developed by John Simpson at the beginning of the 1990s with this in mind, and was initially enthusiastically accepted by interventional cardiologists.

Furthermore, plaque removal can reduce potential plaque shift, facilitate subsequent high-pressure stent expansion (which may increase acute luminal gain), smooth the internal surface of the vessels, scaffold intimal flaps, and prevent elastic recoil[3,4].

Although the clinical registry data were very encouraging, the results of randomized clinical trials (CAVEAT and CCAT) comparing DCA with PTCA showed that debulking did not reduce the restenosis rate and tended to increase 1-year mortality[5,6].

However "optimal DCA" (more efficient intravascular ultrasound [IVUS]-guided plaque removal) led to a lower restenosis rate than PTCA without increasing the number of cardiac events (OARS)[7].

The BOAT study[8] showed that more aggressive debulking using a bigger device and greater plaque excision reduces angiographic restenosis at 6 months, and the GUIDE II study[9] confirmed these results as the IVUS-calculated residual plaque area showed that the final amount of plaque was the main predictor of clinical and angiographic restenosis.

A more recent Japanese randomized study (START) compared aggressive DCA (a residual plaque area of < 50%) with stent implantation: the very aggressive debulking was associated with a lower rate of restenosis (15.8 vs 32.8%, p < 0.05), with no differences in clinical events[10].

Directional coronary atherectomy with stent implantation

Most of the atherosclerotic plaque is displaced but not removed by balloon angioplasty, and may therefore limit optimal stent expansion and the success of the procedure. By removing atherosclerotic plaque, DCA provides the best anatomical conditions for successful stent implantation as it reduces mechanical resistance to vessel wall distension, thus making it easier to expand the stent fully and evenly, and prevent plaque shift. Furthermore, the struts of the stent cover the rough surfaces created by the atherocatheter cuts, and also scaffold the intraluminal intimal flaps: as a result, final luminal diameter may be larger and more regular. Stent implantation after optimal debulking can therefore reduce restenosis. A recent study by our group[3], whose results have been confirmed by other similar studies[4,11,12], found a strikingly low rate of restenosis (6.8%) when this approach was used to treat patients with proximal coronary stenosis, with only 3% of the cases requiring target lesion revascularization. Combined DCA and stent implantation is also feasible and safe in patients with left anterior descending coronary artery (LAD) ostial stenosis, and leads to a high primary success rate, a low incidence of restenosis, and a very low incidence of major follow-up complications[13]. It also leads to good short- and long-term follow-up results as demonstrated with left internal mammary artery bypass grafting in patients with isolated proximal LAD disease[14].

AMIGO[15] is a recent multicenter randomized trial that compared DCA followed by stent implantation with stenting alone: the angiographic restenosis rate was similar in the two groups (26.2 vs 22.1%, p = 0.237), but was significantly lower in the patients undergoing optimal debulking (<n 20% visually estimated residual stenosis) (16.2 vs 31.8%, p = 0.001). However, optimal results were obtained in only 26.5% of the studied cases, and 22 of the 46 centers enrolled fewer than 10 patients (and 12 fewer than 5) over a period of 21 months. The results of the AMIGO trial once again underline that optimal DCA results are strictly related to the operator's experience.

The major limitations of DCA remain the complexity of the procedure, which frequently requires high-support guidewires, and the fact that the rigid housing prevents access to vessels having a tortuous course proximally to the lesion. However, it has been shown that the use of new-generation devices allows atherectomy to be performed safely and effectively even in relatively small vessels.

The Fox Hollow device (FHT, Fox Hollow Technologies, Redwood City, CA, USA) is a new monorail atherectomy catheter designed for more and easier plaque excision. It is compatible with 8F guiding catheters, and has a shorter stiff section and lower-profile cutter than previous devices; both of these advantages allow the good negotiation of more complex anatomies. FHT catheters can be advanced over routine angioplasty wire, thus making them easy to use.

Orlic et al.[16] have published the immediate and mid-term results of a prospective 3-center study of 77 FHT-treated patients with 98 complex lesions (76.6% B2 and C) in relatively small vessels (minimal luminal diameter 2.75 ± 0.51 mm) located in mid-distal artery segments. DCA was successful in 94 lesions (96%), and the angiographic complications were one coronary perforation and one adventitial staining. Target lesion revascularization was required in 13.8% of cases, and target vessel revascularization in 20.3% of the patients; 17 patients experienced target vessel failure. The authors concluded that plaque excision with the new device is safe and effective, leading to a similar 6-month clinical outcome to that obtained using previous atherectomy devices.

Treatment of specific lesions

DCA is efficient in treating complex lesions in which plaque shift may compromise the procedural results, but requires specific expertise.

Eccentric lesions. Very eccentric lesions can be selectively excised with less recoil, a lower risk of dissection, and improved angiographic results[17].

Bifurcations. The treatment of bifurcations may be complicated by plaque shifting, suboptimal final results, and even side-branch occlusion, particularly when the target lesion directly involves the ostium of the side branch (types 1, 3 and 4). The DCA approach to bifurcations includes debulking the main branch, followed by angioplasty or side-branch debulking. Procedural success has been recorded in 97-100% of selected cases, with major complications occurring in 0.3%[18]. CAVEAT-I compared debulking with angioplasty in treatment of bifurcations, and found that the former was associated with a higher success rate (88 vs 74%, p < 0.01) and a lower incidence of restenosis (50 vs 61%, p < 0.01), but led to a higher rate of ischemic complications[19]. Furthermore, Dauerman et al.[20] have reported that, when treating true bifurcation lesions (especially those involving large side branches), DCA with adjunctive PTCA improves the angiographic results and decreases the rate of target lesion revascularization in comparison with PTCA alone. A recent study of the treatment of bifurcations has found that DCA + stenting is associated with a greater acute gain and a larger follow-up minimal luminal diameter in the main

branch than stenting alone; the follow-up rates of restenosis and major cardiac events were also lower, albeit without reaching statistical significance[21].

Restenosis and in-stent restenosis. Debulking has been used to treat post-PTCA restenosis and in-stent restenosis, but was not found to be superior to PTCA[22]. In a recent series of 31 in-stent restenotic lesions, it was found that DCA using an 8F guiding catheter-compatible atherectomy catheter had a favorable safety profile, with events limited to non-Q wave myocardial infarction occurring in 3.6% of patients. However, the secondary endpoint regarding the 6-month incidence of angiographic restenosis showed a high restenosis rate (65%)[23]. It is currently only possible to state that DCA as a stand-alone technique does not seem to lower the incidence of recurrence in this subset of lesions. Furthermore, debulking for in-stent restenosis has been limited by concerns relating to the risk of stent strut disruption[24,25], and the technical difficulties of reaching the target with a large, rigid catheter[26,27].

Ostial lesions. Some studies of percutaneous treatment of LAD ostial lesions have reported disappointing results in terms of primary success and complication rates, with a high 6-month incidence of restenosis[28]. The use of a stent leads to more promising results by preventing elastic recoil and limiting dissections, but plaque shifting beyond the edge of the device may compromise the left main artery or the origin of the circumflex. Treatment of these lesions by means of debulking followed by stent implantation reduces mechanical resistance to vessel wall distension (thus making it easier to inflate the stent fully), and may prevent plaque shifting and scaffold the intraluminal intimal flaps. We have previously demonstrated the efficacy and safety of this procedure[13], and the results have been confirmed by other groups[29].

Left main lesions. Kosuga et al.[30] have reported favorable DCA results in 101 consecutive unprotected left main coronary artery lesions, including a low restenosis rate and a high rate of survival after 3 years. Park et al.[31] have shown that IVUS-guided debulking before stenting further improves outcomes in left main coronary artery bifurcation lesions in patients with normal left ventricular function. The results of a recent study by Hu et al.[32] suggest that the benefits of IVUS-guided DCA can be extended to the treatment of left main coronary artery bifurcation lesions without compromising procedural safety.

Coronary atherectomy in the "drug-eluting stent era": do we still need to debulk?

The recent introduction of drug-eluting stents into everyday clinical practice has revolutionized the field of interventional cardiology by dramatically reducing the restenosis rate to < 10%; however, these data come from randomized trials involving highly selected and homogeneous populations.

In the case of certain complex lesions, drug-eluting stents are subject to the same limitations as bare metal stents. Plaque shift plays a major role in the treatment of some complex lesions, such as those of the ostial LAD or circumflex artery, and bifurcation lesions. Moreover, high-pressure balloon inflation may shift plaque components and lead to suboptimal results at the edges of the stent. In the SIRIUS trial, about 25% of the cases of restenosis in the bare metal stent group were found at the edges of the device; in the patients treated with sirolimus-eluting stents, restenosis at the proximal edge was the cause of about two thirds the cases of restenosis, possibly due to plaque compression and distribution along the vessel rather than intimal hyperplasia. In the more recent E-SIRIUS trial, the restenosis rate at the proximal edge was less evident, but the ratio between the length of the lesion and the length of the stent was 1.7, and about half of the patients received more than one stent[33].

Angiographic restenosis after the implantation of a sirolimus-eluting stent in complex patients is infrequent in the RESEARCH registry, and mainly occurs in association with lesion-based characteristics (independent predictors: the treatment of in-stent restenosis, an ostial location, total stented length, reference diameter, LAD) and diabetes mellitus[34].

The sirolimus bifurcation study published in February 2004[35] found that the use of sirolimus-eluting stents seemed to be feasible and relatively safe in the treatment of coronary bifurcations (stenting of both branches vs stenting of the main branch with provisional stenting of the side branch). However, the very high crossover rate in the group of patients randomized to "one" stent means that the question as to whether to use one or two sirolimus-eluting stents remains unanswered. The total 6-month restenosis rate was 25.7%, and was not significantly different between the double-stenting (28%) and provisional side-branch stenting group (19%). These results indicate an improvement in comparison with historical controls treated with bare metal stents: a low rate of main-branch restenosis and a quite acceptable rate of side-branch restenosis, although the latter remains a problem.

The initially suboptimal procedural results could have been avoided by adopting a different strategy involving the use of DCA in selected patients with complex lesions.

In conclusion, given the possible role of plaque shifting at the edges of the stent (particularly in some cases left main and ostial LAD stenosis, and bifurcations with a large side branch), debulking can be advantageous. However, safety studies should be carried out in order to determine whether plaque excision may cause more wall injury which, when followed by a drug-eluting

stent, may have a negative effect on vessel remodeling, with the subsequent formation of an aneurysm or malapposition, and a greater risk of thrombotic events.

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