Editorial

Plaque Excision Combined With Stent Placement
Can a Poor “Finisher” Become a Good “Starter”? 
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In an effort to enhance long-term patency in the coronary circulation, interventional cardiologists have examined the effects of a plethora of devices designed to improve short-term results and reduce the possibility of restenosis. Two disparate techniques, debulking by means of directional coronary atherectomy (DCA) and arterial scaffolding by stent implantation, have been tested separately in prospective randomized trials with respect to angiographic and clinical restenosis. In this issue of Circulation, Moussa et al combine plaque excision and slotted-tube stent placement in an attempt to show that the 2 methods are synergistic.

DCA to Reduce Restenosis: A Tortured Season
DCA has been tested in several well-designed prospective, randomized comparisons with balloon angioplasty. Two early studies, CAVEAT and CCAT, showed that DCA applied to patients with focal lesions in native coronary arteries resulted in only slight reductions in the rate of restenosis. Specifically, in the CAVEAT trial, in which 1012 patients were randomly assigned to DCA or balloon angioplasty, angiographic restenosis was only slightly reduced, from 57% in the balloon group to 50% in the DCA group; clinical restenosis was unchanged (34% versus 35%). An unexpected and disturbing finding was the excess mortality at 1 year in the DCA group (2.2% for DCA versus 0.6% for PTCA, \( P = 0.035 \)), a finding possibly attributable to the doubling of periprocedural non–Q-wave infarction in patients treated with atherectomy. In the CCAT trial, DCA was performed in patients with isolated stenoses in the proximal left anterior descending coronary artery, and results were similar: a nonsignificant reduction in angiographic restenosis (46% versus 43%) and no decrease in clinical restenosis (30.1% versus 30.6%).

DCA was further evaluated in CAVEAT II, a trial in which 305 patients with saphenous vein bypass graft stenoses were randomized to either DCA or balloon angioplasty. Although initial angiographic success was superior in the DCA arm, there was no significant difference in either angiographic restenosis rates (45.6% for DCA versus 50.5% for PTCA) or target reintervention (18.6% for DCA versus 26.2% for PTCA, \( P = 0.09 \)). Disturbingly, distal embolization, a serious complication of vein graft intervention, was substantially higher in patients undergoing DCA (13.4% for DCA versus 5.1% for PTCA, \( P = 0.012 \)). Although death and Q-wave myocardial infarction were similar in both groups, the rate of non–Q-wave myocardial infarction was higher in patients assigned to atherectomy (16.1% for DCA versus 9.6% for PTCA, \( P = 0.09 \)).

These disappointing results, along with the introduction of stents, resulted in a dramatic reduction in the use of DCA by interventional cardiologists, from \( \approx 15\% \) of percutaneous interventions to 1% to 2%. However, proponents of the technique postulated that the unimpressive results obtained with DCA were due to the premature performance of the randomized trials in a time frame before operators had the opportunity to optimize the method with more vigorous plaque excision. Accordingly, in the Optimal Atherectomy Restenosis Study (OARS), 199 patients with new or restenotic lesions in larger (3.0- to 4.5-mm) coronary arteries had more aggressive debulking with the use of larger devices (usually 7F cutters) intended to achieve \(< 15\% \) residual stenosis, a goal that was achieved in 82% of patients. The rate of major complications (Q-wave myocardial infarction and CABG) was reasonably low at 2.5%, but non–Q-wave myocardial infarctions, defined as CK-MB levels \( > 3 \) times normal, occurred in 14% of patients. Angiographic restenosis was 29%, and target lesion revascularization was 18%, with postprocedure lumen dimensions being a powerful predictor of the occurrence of restenosis. At 1-year follow-up, there was 1 death 3 weeks after the intervention in a patient without procedural complications or CK-MB elevation. The concept of optimal atherectomy was formally tested in the Balloon versus Optimal Atherectomy Trial (BOAT), in which 1000 patients with new lesions in native coronary arteries were randomly assigned to undergo either DCA with aggressive tissue removal (target residual stenosis \(< 20\% \)) or conventional PTCA. Angiographic success was slightly better with DCA, with a superior residual stenosis (15% for DCA versus 28% for PTCA). Importantly, these results were achieved without an increase in death, Q-wave MI, or emergency surgery: 2.8% versus 3.3%. However, the rate of CK-MB elevation \( > 3 \) times normal was more than twice as frequent: 16% for DCA versus 6% for PTCA (\( P < 0.001 \)). Follow-up showed slightly less angiographic restenosis (31% versus 40%) but no difference in target vessel revascularization (17% versus 20%, \( P = 0.33 \)).

In summary, the major DCA trials have shown a better initial angiographic outcome but no long-term clinical benefit compared with balloon angioplasty. The substantially higher incidence of CK-MB elevation noted after DCA has raised
concerns, because late mortality at 3 years has been found to be increased in patients who experienced these enzyme rises. To use a baseball analogy, DCA used as the final technique has been an unsuccessful “finisher.”

**Coronary Stent Implantation: A Long Winning Streak Against Easy Teams**

The publication of STRESS and BENESTENT in 1994 marked a breakthrough in attempts to reduce stenosis in relatively low-risk populations (easy teams): those with new lesions in larger coronary arteries. In these early randomized studies comparing the slotted-tube Palmaz-Schatz stent with balloon angioplasty, the reduction in angiographic restenosis from 42% to 32% (P < 0.05) in STRESS and from 32% to 22% (P < 0.02) in BENESTENT was accompanied by a reduced need for ischemia-driven target revascularization at 6 months. These findings have been extended and confirmed in a variety of patient populations. In a randomized study of 120 patients with isolated stenoses of the left anterior descending coronary artery, angiographic restenosis was reduced from 40% to 19% (P = 0.02), and event-free survival at 1 year was improved from 70% to 87% (P = 0.04) by stent placement. In the Saphenous Vein De Novo (SAVED) trial, 220 patients with lesions in aged (10-year-old) saphenous vein grafts were assigned to coronary stent implantation or balloon angioplasty. There was a trend toward less angiographic restenosis, from 47% to 36% (P = 0.24), but event-free survival at 240 days was significantly decreased, from 38% to 26% (P < 0.04). Remarkably, this was achieved with a lower rate of non-Q-wave myocardial infarction: 11% for PTCA versus 6% for stents (P = 0.13). Subsequent studies in which safe and effective antithrombotic regimens were used have resulted in thrombosis rates of <1%, with low rates of bleeding and vascular complications.

Technological refinements have resulted in second-generation slotted-tube stents, which are substantially easier to deliver to the target site. Because of the ease of use, stenting has been applied to broader patient populations (tougher teams) in whom restenosis rates are not comparable to STRESS/BENESTENT-type patients. This has resulted in a formidable new challenge: the patient with in-stent restenosis. Although target lesion revascularization rates in the 10% range are achievable in patients with discrete new lesions in larger coronary arteries, restenosis is significantly greater in higher-risk patient populations, i.e., those with longer lesions, smaller vessels, chronic total occlusions, and restenosis and diabetes. The mechanism of in-stent restenosis is a result of intimal proliferation and matrix deposition, processes that thus far have proved resistant to conventional transcatheter technology. Although the use of local radiation seems to hold promise in the therapy of patients with stent restenosis, most would agree that effective prevention of in-stent restenosis would be a preferable approach. With 700,000 percutaneous transluminal coronary intervention procedures being performed annually in the United States, 60% of which are accomplished with stent placement, most often in patients with non-STRESS/BENESTENT lesions, in-stent restenosis has emerged as an important clinical problem refractory to traditional therapeu-

**Plaque Removal Followed by Stent Implantation**

In this issue of *Circulation*, Moussa and colleagues studied 71 patients in a prospective registry to test the hypothesis that excision of plaque before stent implantation would improve long-term patency beyond what is attainable by stent placement alone. The study was performed in patients undergoing elective intervention: two thirds of the patients had stable angina, but lesion complexity was frequent in this group: half of the stenoses were located at bifurcation points, and one third of the lesions were nondiscrete (>15 mm in length). As expected, clinical success was high, at 96%. One patient who required emergency bypass surgery subsequently died. Q-wave infarction occurred in 2 patients (2.8%). Again, however, non-Q-wave myocardial infarction, defined as elevation of cardiac enzymes to more than twice normal, occurred in 8 patients (11.3%). Angiographic follow-up in 89% of patients showed a remarkably low angiographic restenosis rate of 10.7%, and target-vessel revascularization was needed in only 6.7% of patients. The authors strengthen the validity of the case for this combined approach by matching the patients in this registry with patients who received only stents and had similar clinical and angiographic characteristics. The improved acute angiographic results—acute gain was 0.3 mm greater in the DCA + stent group—was associated with a significantly lower loss index (0.33 for DCA + stent versus 0.46 for stent alone, P = 0.03). This resulted in a significantly greater follow-up minimal lumen diameter and less residual percent diameter stenosis. More importantly, there was a trend toward a reduction in the need for target lesion revascularization, from 18.7% for stent alone to 6.7% (P = 0.13) in the DCA + stent group. The authors further demonstrated that the lowest loss index was found in patients with low residual percent plaque area (<0.6). The basis for this finding might be that less vessel wall stretch and consequently less vessel wall injury occur if the coronary artery is prepared for stenting by plaque removal. Because intimal hyperplasia is directly related to the degree of vessel wall injury, a lower loss index and greater long-term patency might be expected. Thus, it would make intuitive sense to recast DCA in a new role: as the starter that helps the stent (or “finisher”) achieve an even better record.

**Clinical Implications and Future Directions**

These thought-provoking findings should refocus our attention on the possibility that long-term patency can be enhanced by refining the technical aspects of our initial approach specifically by combining DCA and stenting in a synergistic way. The inherent limitations of drawing sweeping conclusions from pilot data will be addressed in a prospective randomized trial, the Atherectomy before Multilink Improves Lumen Gain and Clinical Outcomes (AMIGO) trial, in which excisional atherecetomy combined with stenting will be tested against stenting alone. In that study, it is anticipated that 750 patients will be entered over a 6-month period. Patients with longer lesions (up to 32 mm) in vessels with reference
diameters of 2.75 to 3.5 mm will be enrolled. Of note, difficult lesion subsets—ie, ostial and bifurcation stenoses and chronic total occlusions—will be included. If the strategy of debulking plus stenting proves superior to stenting alone, we will need to dust off our idle cutters, retrain our interventionists, and give DCA another chance for a place in the sun, but only as a “starter.”

References


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