EDITORIAL COMMENT

Is it Time to Offer Elective Percutaneous Treatment of the Unprotected Left Main Coronary Artery?*

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As the techniques for catheter-based intervention continue to be refined, up to 35% of patients who undergo diagnostic catheterization are referred for such therapy, while only roughly 25% are referred for bypass surgery. Much of this growth in the use of catheter-based intervention has come from the treatment of patients who previously received medical therapy (e.g., those with acute myocardial infarction or mild angina with a positive functional study, etc.) although some of the growth clearly has come from treating patients once considered the exclusive province of bypass surgery (e.g., those with anatomically-suitable multivessel disease). One of the remaining bastions of surgical dominance, however, has been patients who have “significant” (>50% or certainly >70% diameter stenosis) narrowing of the left main coronary trunk, as found in 7% to 10% of all diagnostic catheterization procedures. This preference for surgical revascularization is based on trials conducted in the late 1970s, which demonstrated that surgery reduced (from roughly 29% to 7%) the substantial three-year mortality seen from the treatment of patients who previously received surgery (e.g., those with anatomically-suitable multivessel disease). The issue in question, however, is whether interventional techniques should be considered as an option for the unprotected left main lesion. High-quality data on the subject have been difficult to come by and frequently anecdotal. In 1997, Ellis collected 107 such patients who had undergone treatment at one of 16 international centers between 1994 and 1996, representing only 0.2% of interventional procedures at those institutions (4). Procedural and long-term outcome varied significantly with baseline status, being substantially worse for patients who had acute myocardial infarction or other factors (advanced age, left ventricular dysfunction, renal or cerebrovascular disease) that rendered them high-risk for operation. Despite stent placement in only half of the cases, the technical success was generally high (96.4%), and the in-hospital mortality in the elective patients was low (3.6%), particularly compared with the 35% to 40% mortality in nonselective patients. With limited use of stents (14% of cases), the angiographic restenosis rate in the elective patients was high (40%). Through multiple repeat catheter-based interventions for its treatment, however, the three-year mortality was 22.5% for elective patients (5% in the 33 patients deemed to be low risk for coronary artery bypass grafting (CABG and 30% in patients deemed to be high risk for CABG).

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When stents are used routinely for left main intervention, even better results may be obtained. Park et al. (6) reported 42 patients with normal left ventricular function who were treated by stenting with a 100% success and no in-hospital complications. One-year mortality was 2.5%, but seven patients (17%) developed recurrences that presented with unstable angina at a mean of two months, leading to bypass in five of the patients and repeat catheter treatment in the remaining two. Wong et al. (7) reported a series of purely elective stent procedures in 55 patients (drawn from 66 with that anatomy on diagnostic angiography). The procedural success was 100%, with no major complications. Eleven patients (20%) had symptomatic recurrence, which was managed by CABG in seven patients and repeat intervention in two patients, with only one late death (2%).

These data are reinforced by the findings of the current paper by Silvestri et al. (8), which reports the results in 140 elective left main stent procedures, including 47 patients deemed to be at high risk for CABG (age >75 years, ejection fraction <35%) and 93 patients deemed to be at low risk for CABG. Procedure success was 100%, with a 30-day mortality of 6% (9% in the high risk and 0% in the low risk patients). One-year target lesion revascularization was 18% (three-quarters surgical), and one-year mortality was 8% (11% in the high risk and 2.5% in the low risk subsets) including noncardiac events. These results for elective stenting both in patients deemed to be at low risk for surgery (i.e., a 2% to 5% one-year mortality) and those deemed to be at higher risk (i.e., a 10% one-year mortality) for the first time approach those provided by the gold standard of bypass surgery. Given the stability of stented lesions after one year, these favorable results will most likely be maintained over longer follow-up.

Before recommending broad application of catheter based treatments for unprotected left main disease, however, it is important to more fully address the two remaining challenges: first, we must develop a reliable way to deal with the substantial number of lesions that involve the distal left main bifurcation and extend into the left coronary branches, which accounted for more than half of the cases in the Silvestri series. Silvestri’s practice of finishing such procedures with “kissing balloon” inflations extending into the proximal left anterior descending and circumflex may help, but is unlikely to suffice as a reliable treatment of true distal left main bifurcation lesions. Debubbling techniques (often directional or rotational atherectomy followed by stenting) appear to be helpful in such lesions, but were used infrequently (6% of cases) here. The development of new-generation stents that allow a variety of bifurcation stenting approaches will be essential. Second, we must work on better techniques for preventing, detecting and managing left main restenosis—a problem that may present with late sudden death in this unprotected population. The dictum of “bigger is better,” so well established elsewhere in the coronary tree (9), also applies to the left main, with much lower clinical recurrence rates when a larger final lumen area can be obtained (target lesion revascularization rates of 50% for <7 mm$^2$, 10% for 7–9 mm$^2$, and 5% for final CSA >9 mm$^2$ [equivalent to ~3.5 mm in minimum diameter] (10). It is important to recognize, however, that none of our current techniques eliminates restenosis and that we must aggressively monitor such patients if we are to mitigate the potential lethality of restenosis in the unprotected left main. One approach is the performance of routine two to three month follow-up angiography to detect aggressive restenosis (estimated incidence ~20%) and then refer such patients to surgery, as has been done in most of the series described above. Perhaps when intracoronary brachytherapy techniques are approved by the FDA (possibly as soon as mid 2000), radiation at the time of initial treatment or during the treatment of the first recurrence (11) may allow more definitive and durable catheter-based treatment.

Speaking from the current perspective, however, most patients with significant left main disease who are acceptable candidates for bypass surgery should probably still undergo that proven and effective therapy, particularly if the left main lesion is just one part of complex multivessel disease. One exception may be patients judged to be at prohibitively high surgical risk and who are anatomically suitable for catheter-based treatment. They may undergo stenting with aggressive attempts to maximize the lumen diameter (including present rotational atherectomy whenever calcium is present or expansion of the predilatation balloon is impeded at moderate pressure). For anatomically suitable patients who are at low risk for bypass surgery but are averse to surgery and understand the risks and unproved benefit of left main stenting, there may be some latitude to allow selective use of catheter-based techniques by experienced operators (perhaps under protocols sanctioned by the local Institutional Review Boards). Such elective stenting of left main patients deemed at low risk for bypass surgery should, however, undergo the careful randomized evaluation it deserves before becoming the “standard of care.” An equivalence trial design assuming a one-year mortality of 8% with surgery and a delta of 6% could be performed with as few as 500 patients but showing equivalency to within a smaller delta (e.g., 2% to 3%) would require an impractically-large trial of several thousand patients. Until a trial shows the substantial equivalence of left main stenting to surgery in lower risk elective patients suitable for surgery, acceptance of catheter-based left main interventional in such patients based only on current anecdotal evidence would (however encouraging) seem premature when the highly effective surgical option is readily available.

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REFERENCES


