Usefulness of a Prototype Directional Catheter for Excimer Laser Coronary Angioplasty in Narrowings Unfavorable for Conventional Excimer or Balloon Angioplasty

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We report clinical and angiographic results in 53 patients with 57 significant coronary or saphenous vein graft narrowings treated with directional excimer laser angioplasty. The target vessels were the left main (1%), anterior descending (19%), circumflex (19%), right coronary artery (39%), and vein grafts (9%). Lesions were morphologic class B1 (18%), B2 (79%), or C (3%), with 40 de novo and 17 restenotic lesions. Adjunctive balloon angioplasty was used in 53 lesions (93%). Mean pre- and postprocedural minimal lumen diameters were 0.6 ± 0.3 and 1.9 ± 0.7 mm (p < 0.001), corresponding to a mean diameter stenosis of 72 ± 20% and 27 ± 16%. Procedural success rate was 91%. Cumulative risk of death, Q-wave myocardial infarction, or emergency bypass operation was 9% (5 patients). Of patients who had a successful laser procedure, 28 (60%) with 30 lesions underwent angiographic follow-up at 6 ± 3 months after the procedure. Restenosis rates (>50% diameter restenosis or acute gain loss) were 37% and 23%, respectively. Four patients underwent bypass, 3 angioplasty, and 1 patient died from cancer. This study demonstrates the feasibility of directional application of laser energy to selected unfavorable narrowings for conventional excimer laser or balloon angioplasty. Further evaluation of this device using the now standard saline infusion technique is necessary to establish its ultimate role as a primary interventional device.

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Excimer laser angioplasty using concentric over-the-wire catheters is an effective therapy for selected complex coronary artery lesions. Favorable lesion morphology for excimer laser angioplasty includes long lesions, diffuse disease, chronic total occlusions, and aortoarterial lesions. Eccentric lesions, lesions on bend points, and bifurcation lesions, however, are associated with higher procedure complication rates including abrupt closure, perforation, and coronary dissections. A prototype laser catheter with an eccentric fiber-optic bundle and a rotatable tip has been developed in an attempt to provide directional control of intravascular delivery of laser energy. We report acute and follow-up results with this directional laser angioplasty catheter in 53 consecutive patients treated at a single center.

METHODS

Laser catheter: The directional laser catheter (model P.C. 4045, Advanced Interventional Systems, Irvine, California) was constructed of multiple fibers arranged eccentrically around a guidewire lumen. The catheter is 1.8 mm in diameter. The proximal shaft has a torque knob that allows the operator to rotate the distal end of the catheter under fluoroscopic guidance. The eccentric fiber-optic bundle is placed in contact with the target plaque. One of the potential advantages of this catheter is an eccentric nose tip that extends beyond the fiber bundle protecting the contraextrafmal vessel wall.

Patient group: Between March 1992 and June 1994, 58 patients with 62 coronary or saphenous vein graft narrowings were scheduled to be treated with the directional catheter. The device was used under an Investigational Device Exemption and the protocol was approved by the Institutional Review Board. All patients gave informed consent. In 4 patients, the laser procedure was not performed because the narrowings could not be crossed with guidewires. One patient was excluded from angiographic analysis because of poor quality cineangiography. Patients were considered for the directional excimer procedures if they had complex lesions considered to be suboptimal for conventional balloon or laser angioplasty. These lesions were all either highly eccentric, on bend points, or at bifurcations in vessels of small to medium caliber.

Laser procedure: Patients were premedicated with aspirin (325 mg/day) and calcium channel antagonists. An initial intravenous heparin bolus dose of 10,000 U was given, and additional heparin was titrated to maintain the activated clotting time of >350 seconds. Standard 9Fr guide catheters were used. The lesion was crossed with a conventional guidewire and the laser catheter was advanced until its tip was just proximal to the lesion. The catheter was rotated so that the fiber bundle was aligned with the lesion. Lasing was initiated by ad-
vancing the catheter at a rate of approximately 1 mm/s, maintaining close contact between the fiber tip and the lesion. Saline flushing of the coronary artery was not performed and the number of lasing passes were at the discretion of the operator.

Data analysis: All clinical data were prospectively collected. Cineangiograms were analyzed by 2 observers without prior knowledge of the outcome. Stenosis severity was measured using an automated computer-assisted edge-detection algorithm (Imagecomm Systems, San Jose, California). The projection that best demonstrated the target lesion was selected throughout the study. End-diastolic frames with the most severe narrowing were selected and the following baseline measurements were obtained: (1) reference vessel diameter, (2) minimal lumen diameter, (3) lesion length (>50% luminal narrowing), and (4) percent diameter stenosis. Quantitative analysis of vessel angle, lesion angle, and eccentricity index was performed as previously described. Cineangiograms were reviewed for the following morphologic characteristics: presence of calcification, thrombus, ulcer, bifurcation, and branch or ostial involvement. Morphologic characteristics were assessed for each lesion and the definitions used were similar to those adopted by Ghaazal et al. Final procedure success was defined as <50% residual diameter narrowing in the absence of major events during hospitalization (Q-wave myocardial infarction, death, need for revascularization). Infarction was diagnosed if the total creatine kinase level was >200 IU/L with the excimer laser catheter. After placement of a coronary stent, the patient developed a toxic pulmonary reaction to dextran and fatal respiratory distress syndrome. Angiographic complications included intimal tear (18%), dissection (11%), thrombus (11%), and vessel occlusion (5%).

Clinical and angiographic follow-up: Clinical follow-up was obtained in 46 patients (98%) with initial procedure success. Twenty-eight patients (60%) with 30 lesions underwent angiographic follow-up at 6 ± 3 months after the laser procedure. The remaining 18 patients were lost due to multiple lesion intervention. Death was secondary to balloon-induced dissection in an artery other than the one treated with the excimer laser catheter. After placement of a coronary stent, the patient developed a toxic pulmonary reaction to dextran and fatal respiratory distress syndrome. Angiographic complications included intimal tear (18%), dissection (11%), thrombus (11%), and vessel occlusion (5%).

RESULTS

The cohort included 53 patients (46 men and 7 women, mean age 67 ± 10 years) and a total of 57 lesions, 70% new-onset and 30% restenotic. Target vessels were the left main (1%), anterior descending (32%), circumflex (19%), right coronary artery (39%), and vein grafts (9%). Lesions were morphologic class B1 (18%), B2 (79%), or C (3%) according to the American College of Cardiology/American Heart Association criteria, with 8 animal (14%), 7 bifurcation (12%), and 16 branch lesions (28%). Moderate to heavy calcification was present in 13 lesions (23%), ulceration in 11 (19%), and thrombus in 3 (5%). Mean vessel angle was 29 ± 25°, lesion length 4.3 ± 2.3 mm, and eccentricity index 27 ± 10, with 18 lesions (32%) having an index of >30. Mean reference vessel diameter was 2.7 mm. An adjunctive balloon angioplasty was performed in 53 lesions (93%). The Palmaz-Schatz coronary stent was successfully deployed in 3 patients (6%) with postlaser dissections.

Minimal lumen diameter increased from 0.6 ± 0.3 to 1.3 ± 0.5 mm after laser and 1.9 ± 0.7 mm after balloon angioplasty (p < 0.001), yielding a residual stenoses of 52 ± 19% and 27 ± 16% (p < 0.001, respectively). The overall procedure success rate was 91%. Major ischemic clinical complications occurred in 5 (9%) patients. One had myocardial infarction, 2 needed a bypass operation, and 1 patient was referred for bypass surgery in the setting of acute infarction. One more patient had non-Q-wave myocardial infarction, with a creatine kinase level of 760 IU/L. One patient died 2 weeks after multiple lesion intervention. Death was secondary to balloon-induced dissection in an artery other than the one treated with the excimer laser catheter. After placement of a coronary stent, the patient developed a toxic pulmonary reaction to dextran and fatal respiratory distress syndrome. Angiographic complications included intimal tear (18%), dissection (11%), thrombus (11%), and vessel occlusion (5%).

DISCUSSION

The directional laser catheter was designed to overcome some inherent limitations of the concentric excimer catheters. The eccentric systems are less effective in highly eccentric lesions, lesions at bend points, or bifurcation lesions. Our data demonstrate the feasibility of applying a directionally emitting excimer catheter to lesions.

Quantitative angiographic analysis revealed moderate improvement in mean minimal lumen diameter from 0.6 ± 0.3 to 1.3 ± 0.5 mm. If one excludes the lesions in which angiographic complications occurred, the postlaser minimal lumen diameter is 1.6 ± 0.4 mm, close to the 1.8 mm diameter size of the directional catheter. Most patients required adjunctive balloon angioplasty to achieve acceptable final angiographic results, and at follow-up there was a mean loss of approximately 0.5 mm in the selected cohort that underwent repeat angiographic examination secondary to clinical indications. The dichotomous target vessel restenosis rates were 37% and 23% by the 2 common definitions. The study cohort is too small and the angiographic follow-up too incomplete to draw definitive conclusions, although these numbers are very respectable in view of the complex lesions and relatively few patients in whom follow-up angiography was performed.

Both the angiographic and clinical complication rates for the study were relatively high. Complete occlusion...
occurred during the procedure in 5% of lesions, and some form of intimal tear or dissection was seen in 29% of lesions. These complication rates may be partly due to the fact that this study was performed without using the saline infusion technique. It is now known that laser ablation, when applied in blood or radiographic contrast, is associated with rapidly expanding and collapsing vapor bubbles, and these may be causal in vascular dissection and acute occlusion. It has been well demonstrated that infusion of saline before and during the excimer laser ablation markedly reduces the rate of significant dissection. Had the saline infusion technique been used in this cohort, there might have been improvement in the relatively high rate of vascular dissection.

This study demonstrates the feasibility of applying directional laser energy to relatively complex lesions unfavorable for other interventional techniques. Further study using the now standard saline infusion technique would be of value to further evaluate the role of a directional laser catheter.


