Excimer Laser–Facilitated Coronary Angioplasty
Relative Risk Analysis of Acute and Follow-up Results in 200 Patients

John A. Bittl, MD, and Timothy A. Sanborn, MD

Background. Excimer laser coronary angioplasty has been reported to be a promising treatment for complex coronary artery disease. The purpose of this study was to define the predictors of acute success and restenosis after this experimental intervention.

Methods and Results. A cohort of 200 consecutive patients had a minimum of 6 months of follow-up after treatment of 215 coronary stenoses that were carefully selected for excimer laser coronary angioplasty. At the time of the initial procedure, the laser catheter alone produced a residual stenosis of ≤50% at 119 of 215 lesions (55.4%). For complete dilatation, 87.9% of the lesions required adjunctive balloon angioplasty. Clinical success was achieved in 183 of the 200 patients (91.5%), as indicated by a reduction by at least 20% of the narrowing of the vessel diameter, ≤50% residual stenosis, and no in-hospital complication. Complications included abrupt closure (5.0%), myocardial infarction (3.5%), bypass surgery (3.0%), perforation (2.0%), and death (0.0%). Logistic regression analysis showed that lesions at vessel bifurcations (success rate, 66%; adjusted odds ratio [OR] = 0.16; p = 0.002) or in tortuous vessels (success rate, 82%; OR = 0.48; p = 0.004) were associated with decreased clinical success. However, acceptable success rates were achieved in patients with lesions in saphenous vein grafts more than 3 years old (success rate, 94%; OR = 1.40; p = 0.75), in ostial lesions (success rate, 100%; OR = 3.36; p = 0.43), and in lesions longer than 10 mm (success rate, 93.5%; OR = 1.50; p = 0.39). Clinical follow-up was available in 197 of the 200 patients (98.5%) a mean of 5.9 ± 1.9 months after angioplasty, at which time 31.0% of patients had developed symptoms or evidence of ischemia. No patient died during the study. Follow-up angiography was obtained in 83.1% of eligible patients after a mean [±SD] of 5.2 ± 2.0 months. Angiographic restenosis, defined by >50% stenosis, appeared at 78 of 164 lesions (47.6%). By logistic regression analysis, only lesions in saphenous vein grafts were associated with a decreased rate of restenosis (restenosis rate, 20%; OR = 0.18; p = 0.01).

Conclusions. This analysis, which defines the profile of risk for excimer laser angioplasty, provides a sound basis for rigorous comparison of adjunctive excimer laser with balloon angioplasty for ostial narrowings, long lesions, and saphenous vein graft stenoses. (Circulation 1992;86:71–80)

Key Words: coronary artery disease • perforation • percutaneous transluminal coronary angioplasty • angina pectoris • excimer laser

Since its introduction in 1977, balloon angioplasty has undergone major improvements but has persistent shortcomings: a 6.8–7.3% rate of abrupt closure1–2 and a 17–49% rate of angiographic restenosis.3–5 Balloon angioplasty has lower success rates in long lesions,6,7 calcified vessels,7 bifurcation lesions,8 saphenous vein graft stenoses,9 and ostial narrowings.10,11 It is possible that some of these angiographic characteristics, which have been identified as relatively complex by the American College of Cardiology/American Heart Association (ACC/AHA) Task Force,12 may be handled more effectively by a procedure that removes atherosclerotic plaque such as excimer laser coronary angioplasty. Recent studies have reported that excimer laser–facilitated coronary angioplasty, in contrast to balloon angioplasty, is equally successful in treating simple and complex lesions.13,14

In this study, we analyzed results in 200 consecutive patients who had 6 months of follow-up evaluation after excimer laser coronary angioplasty to define the determinants of acute success and restenosis with the new treatment.

Methods

Patient Enrollment

Beginning on May 8, 1989, patients were enrolled for excimer laser–facilitated coronary angioplasty at Mount Sinai Medical Center, New York, or Brigham and Women's Hospital, Boston, if they had evidence of angina or provokable ischemia associated with lesions that were judged to be approachable with the laser catheter. Almost all patients could have been treated with balloon angioplasty but were enrolled in this study because of patient and physician preference. All patients were surgical candidates and had an ejection fraction >30.

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We attempted to enroll patients with a broad representation of stenosis complexity, but not all lesion types were judged to be suitable for treatment with relatively stiff laser catheters. Using the ACC/AHA classification for balloon angioplasty,\textsuperscript{12} we prospectively declared certain lesion types contraindicated for treatment with excimer laser coronary angioplasty. Whereas all type A lesions were judged to be suitable for treatment (length <10 mm, discrete, concentric, readily accessible, <45° angle, smooth contour, little or no calcification, less than totally occluded, not ostial, no major side branch involvement, absence of thrombus), several type B characteristics were contraindicated (angle >45° but <90°, heavy calcification, and some thrombus present). Other type B lesions were believed to be amenable to laser angioplasty (length, 10–20 mm; eccentric, moderate tortuosity of proximal segment, irregular contour, total occlusion <3 months, ostial, bifurcation lesion requiring two guide wires, and moderate calcification). Only about half of the type C lesions were suitable for laser angioplasty (length >20 mm, total occlusion >3 months, degenerated vein graft, or inability to protect major side branches with a guide wire), but many type C lesions were contraindicated (excessive tortuosity of proximal segment, extremely angulated >90°, or large thrombus present).

A total of 1,202 cases were screened for possible excimer laser angioplasty at the two hospitals. After discussion with referring physicians and review of diagnostic coronary arteriograms, 209 patients were formally asked to participate in the study. Three patients refused treatment with excimer laser angioplasty and underwent balloon angioplasty alone. Six patients had total occlusions that could not be recanalized with a guide wire, and no laser catheter was used. Thus, of 1,202 patients screened, 200 patients (16.6%) gave informed consent and underwent excimer laser angioplasty.

All patients were requested to have clinical follow-up with exercise treadmill testing at 1, 3, 6, and 12 months and to undergo follow-up angiography 6 months after laser angioplasty.

The protocol was approved by the Institutional Review Boards of the two hospitals.

Definitions

Lesion complexity was graded according the classification of the ACC/AHA Task Force\textsuperscript{12} as modified by Ellis et al\textsuperscript{15} to include types B1 and B2, depending on whether one or more complex features were present. Multivessel disease was defined by the presence of two or three-vessel disease, according to the definitions of the Coronary Artery Surgery Study.\textsuperscript{16} Clinical success was defined according to the National Heart, Lung, and Blood Institute (NHLBI) criteria as a reduction by ≥20% of the narrowing of the vessel diameter, ≤50% residual stenosis after laser angioplasty (with or without adjunctive balloon dilatation), and the absence of a major complication at any time during hospitalization (death, Q wave or non-Q wave myocardial infarction, or need for emergency coronary artery bypass surgery).\textsuperscript{17} Clinical restenosis was defined by recurrence of angina, positive exercise treadmill test, development of myocardial infarction, or need for revascularization. Recurrence of angina was defined by the presence of class I or higher angina (Canadian Cardiovascular Society). A positive exercise test was defined by the production of anginal symptoms or ≥1.0-mm ST segment depression even for patients with multivessel coronary artery disease. Angiographic restenosis was indicated by the presence of >50% stenosis at the treated site at any time during follow-up. Although patients were scheduled for follow-up angiography 6 months after excimer laser angioplasty, some returned earlier: Freedom from angiographic restenosis referred to ≤50% stenosis on angiography performed >3 months after angioplasty because >90% of restenosis after angioplasty occurs within 3 months.\textsuperscript{5}

Excimer Laser System for Coronary Angioplasty

Percutaneous excimer laser coronary angioplasty was performed with the CVX-300 system (Spectranetics Corporation, Colorado Springs, Colo.), which is a xenon chloride excimer laser system that operates at 308 nm with an average pulse duration of 135 nsec and mean output of 200 mJ/pulse at nominal voltage operation. The laser catheters used in this study were multifiber, over-the-wire, “end-firing” catheters with diameters of 1.4, 1.7, or 2.0 mm, containing an array of 100-μm optical fibers arranged coaxially around a 0.022-in. (0.56-mm) central lumen. Excluding the central lumen, optical fibers comprised 34%, 27%, and 19% of the total surface area at the tips of the 2.0-mm, 1.7-mm, and 1.4-mm catheters, respectively.

The laser catheter was advanced through a coronary guide catheter (Schneider, Minneapolis, Minn.; 8F for 1.4-mm and 1.7-mm catheters and 9F for the 2.0-mm laser catheter) seated at the origin of the coronary artery. The position of the laser catheter in the coronary artery was confirmed by injecting 3 ml of Hypaque-76 (diatrizoate meglumine and diatrizoate sodium, Winthrop, N.Y.) under cineangiography. Laser output from the generator was activated with a foot pedal as the catheter was advanced slowly through the stenosis. Although advancement of the catheter was difficult to control precisely, attempts were made to push the catheter very slowly at an average rate of 0.5 mm/sec so as to not exceed the rate of tissue ablation.\textsuperscript{18} Laser energy was delivered in pulses of 135 nsec, at a frequency of 25 sec\textsuperscript{-1}, in trains of 0.04–5.0-second duration, and at a fluence of 30–60 mJ/mm\textsuperscript{2}. Fluence, a measure of energy density, was measured directly at the catheter tip with a joule meter before and after angioplasty.

Qualitative and Quantitative Coronary Angiography

Both investigators determined lesion severity by visual assessment for all patients before treatment, after laser, and after adjunctive balloon angioplasty, and at follow-up without the use of a core laboratory. To validate the visual assessment of stenosis severity, a subset of 95 patients who had suitable films was selected from the first 119 consecutive patients to have quantitative analysis of coronary arteriograms performed with both digital caliper and videodensimetric methods before and after laser and balloon angioplasty and at follow-up. Patients were selected for computer quantification if they had segments that were free from overlapping vessels, contained no side branches, and were at least 8 mm in length. The selection of patients for quantitative analysis was made.
solely on the basis of technical suitability for analysis. Clinically successful laser angioplasty was achieved in 86 of the 95 patients (90.5%) who had films analyzed. A Fisher imaging DF-100 digital subtraction angiographic unit coupled to a Phillips Cardiodiagnostic 100 x-ray generator was used at Mount Sinai Medical Center as previously described. 19 At Brigham and Women's Hospital, the involved segments were digitized at 20–40 μm/pixel by use of a video camera (Cohu, San Diego, Calif.), a video interface (TRAPIX SS 92U, Recognition Concepts Inc., Reno, Nev.), and a MicroVax II computer (Maynard, Mass.). Four cine frames were scanned and averaged, with two fixed anatomic features serving as references to ensure accurate alignment. Sixteen video images of each cine frame were summed to reduce video noise, and two-line profile averaging was used to minimize anatomic noise. 20

### Statistical Analysis

Logistic regression analysis was used to identify predictors of clinical success and restenosis from a series of clinical (age, sex, unstable angina, diabetes, hypertension, history of myocardial infarction, and multivessel disease), angiographic (lesion complexity and previous angioplasty), and procedural (laser parameters, adjunctive balloon angioplasty) variables. 22 Adjusted odds ratios (OR) have been provided to estimate the probability that a given variable increased or decreased success compared with all other patients without the variable. 22 Logistic regression analysis and calculation of ORs with 95% confidence limits for clinical success and restenosis were performed with a standard statistical package (Systat 5.1 and LOGIT 2.0, Evanston, Ill.). Of the variables evaluated, those found to have borderline significance on univariate analysis (p < 0.25) were included in the multivariate analysis. Linear regression analysis was used to compare visual assessment versus quantitative angiographic assessment of stenosis severity. One-way ANOVA was performed to identify differences in lumen diameter according to catheter size. Repeated-measures ANOVA was used to measure changes in percent diameter stenosis and minimal lumen diameter before treatment, after laser, after balloon angioplasty, and at follow-up. When a significant result was obtained by ANOVA, Scheffe's test for multiple comparisons was used to identify significant differences for each variable at the four observation times. 23 All data are shown as mean ± SD.

### Results

**Patients**

Excimer laser–facilitated coronary angioplasty was attempted in 200 consecutive patients. The average age of the patients was 58 years, and 80.5% of the patients were men. More than 80% of the patients had Canadian Cardiovascular Society class III or IV angina before treatment (Table 1).

The 200 patients had a total of 215 stenoses that were intended for treatment with excimer laser coronary angioplasty (Table 2). Lesions involved the three coronary arteries and saphenous vein bypass grafts. According to a classification of lesion severity, 15.8% of lesions were characterized as type A or simple lesions, whereas 65.6% were moderately complex (type B), and 18.6% were complex (type C). Of the 34 type A lesions,
FIGURE 1. Images of salvage excimer laser for failed balloon angioplasty. An 88% stenosis in the ostium of a 7-year-old saphenous vein graft (panel A) could not be dilated fully with balloon angioplasty despite inflation pressures >15 atm (panel B). After excimer laser angioplasty, a 32% stenosis remained (panel C) that was dilated further with balloon angioplasty to a residual stenosis of 10% (panel D) and found to be unchanged at follow-up angiography (panel E).

12 were restenosis lesions and 22 were in the proximal segment of the left anterior descending coronary artery. An example of a complex lesion that could not be dilated with balloon angioplasty is given in Figure 1.

Success and Complication Rates

The laser catheter alone reduced stenosis severity by ≥20% in 178 of 215 lesions (82.8%). However, the relatively small laser catheters alone produced a residual stenosis of ≤50% at only 119 of 215 lesions (55.4%). For more complete dilatation, 189 of the treated sites (87.9%) required adjunctive balloon angioplasty to achieve the smallest residual stenosis and largest lumen possible. Clinical success was achieved in 183 of the 200 treated patients (91.5%).

The in-hospital complication rates are shown in Table 3. The risk of acute myocardial infarction at any time during hospitalization was 3.5%. No patient experienced a Q wave myocardial infarction. Abrupt closure occurred in the cardiac catheterization laboratory in seven patients (3.5%) and later in the hospital in three other patients (1.5%). All were successfully treated with repeat balloon angioplasty. Excimer laser coronary angioplasty was not used to treat abrupt closure. Bypass surgery was required at some time during hospitalization in six patients (3%), three of whom required this on an emergency basis.

Eleven patients (5.5%) showed evidence of significant dissection that impaired flow, resulted in myocardial infarction, or required bypass surgery. Four patients
TABLE 3. Complications in Excimer Laser–Facilitated Coronary Angioplasty in 200 Patients

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bypass surgery during hospitalization</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Q wave or non-Q wave myocardial infarction</td>
<td>7</td>
<td>3.5</td>
</tr>
<tr>
<td>Abrupt closure</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Dissection</td>
<td>29</td>
<td>14.5</td>
</tr>
<tr>
<td>Minor</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td>Clinically significant*</td>
<td>11</td>
<td>5.5</td>
</tr>
<tr>
<td>Perforation</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Minor extravasation</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Free, requiring surgery</td>
<td>1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Complications include death, myocardial infarction, or bypass surgery required at any time during hospitalization.

*Associated with major complication of death, myocardial infarction, bypass surgery, or producing ≥TIMI grade 2 flow.

(2.0%) experienced perforation of the coronary artery during laser angioplasty. All perforations occurred with the 1.7-mm catheter. One patient required emergency surgery for a persistent perforation in the left anterior descending coronary artery associated with a bend of 40°. Two patients had small perivascular collections of contrast medium at ostial stenoses after passage of the laser catheter. Both patients were treated with 2-minute balloon inflations, and neither experienced abrupt closure or myocardial infarction or showed evidence of pseudoaneurysm formation at follow-up angiography. The fourth patient had an uneventful course after 25-minute inflation of the Stack perfusion catheter (Advanced Cardiovascular Systems, Temecula, Calif.) at the perforation site, which occurred in the midportion of the right coronary artery at a bend of 45°.24 The 215 lesions were treated with a total of 210 laser catheters. The incidence of complications was not affected by catheter size, although the analysis is limited by small numbers of 1.4-mm (n=22) and 2.0-mm (n=21) catheters.

Angiographic Analysis

We used computer-assisted quantitative coronary angiography in 95 patients with technically suitable films (Figure 2). The clinical success rate in this subgroup was 90.5%. Laser treatment alone increased minimal lumen diameter from 0.5±0.3 mm to 1.5±0.6 mm (p<0.05) and improved percent diameter stenosis from 87±9% to 50±21% (p<0.05). Adjunctive balloon angioplasty increased minimal lumen diameter further to 2.3±0.5 mm and improved the stenosis severity to 21±14% (p<0.05).

However, at restudy, an average of 5.2±2.0 months later, the mean minimal lumen diameter had decreased to 1.2±1.0 mm and percent diameter stenosis had increased to 56±32% (p<0.05).

Lumen diameter at follow-up did not correlate with the postlaser lumen diameter (r=0.09; p=0.49) but did correlate with the postprocedural lumen diameter after adjunctive balloon angioplasty (y=0.6x–0.1; n=57, r=0.31, p=0.02).

The influence of the three laser catheter sizes on minimal lumen diameter was evaluated by quantitative coronary angiography. After laser treatment alone, minimal lumen diameter increased from 0.5±0.4 mm to 1.2±0.5 mm (1.4-mm catheter, n=5), 1.5±0.6 mm (1.7-mm catheter, n=76), or 1.9±0.4 mm (2.0-mm catheter, n=9) (p=0.06 by ANOVA). After adjunctive balloon angioplasty, the minimal lumen diameter increased further to 2.1±0.4 mm (1.4-mm catheter, n=5), 2.2±0.5 mm (1.7-mm catheter, n=74), or 2.5±0.7 mm (2.0-mm catheter, n=9) (p=NS by ANOVA).

The effect of laser therapy on stenosis severity was evaluated by visual assessment in 182 consecutive patients (Figure 3). Compared with quantitative angiography, visual assessment consistently overestimated stenosis severity before treatment (90±7% by visual assessment versus 83±9% by quantitative angiography; p=0.0001, n=95). In contrast, similar results were obtained with the two methods after treatment with laser (52±20% versus 46±22%; p=0.07, n=95), after adjunctive balloon angioplasty (22±16% versus 19±12%; p=0.15, n=93), and at follow-up angiography (56±31% versus 56±34%, p=0.92, n=57).

Clinical and Angiographic Restenosis

Clinical follow-up was obtained in 197 of the 200 patients (98.5%). Three patients could not be reached for follow-up (family members reported that one patient left the country and two others moved out of state). Of
TABLE 4. Logistic Regression Analysis for Predictors of Clinical Success in 200 Patients

<table>
<thead>
<tr>
<th>Clinical variables</th>
<th>Odds ratio (95% CI)</th>
<th>Univariate</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.05 (1.01,1.10)</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>Female sex</td>
<td>3.78 (0.48,29.5)</td>
<td>0.21</td>
<td>0.22</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>1.71 (0.55,5.32)</td>
<td>0.46</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.40 (0.13,1.23)</td>
<td>0.10</td>
<td>0.99</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.62 (0.48,5.48)</td>
<td>0.53</td>
<td></td>
</tr>
<tr>
<td>History of myocardial infarction</td>
<td>0.94 (0.32,2.70)</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>Multivessel disease</td>
<td>0.56 (0.20,1.61)</td>
<td>0.28</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Angiographic or procedural variables</th>
<th>Odds ratio (95% CI)</th>
<th>Univariate</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous PTCA</td>
<td>1.85 (0.63,5.40)</td>
<td>0.26</td>
<td></td>
</tr>
<tr>
<td>Left anterior descending coronary artery</td>
<td>1.87 (0.71,4.94)</td>
<td>0.21</td>
<td>0.73</td>
</tr>
<tr>
<td>Right coronary artery</td>
<td>0.29 (0.11,0.77)</td>
<td>0.01</td>
<td>0.06</td>
</tr>
<tr>
<td>Circumflex artery</td>
<td>4.51 (0.26,77.5)</td>
<td>0.31</td>
<td></td>
</tr>
<tr>
<td>Saphenous vein graft</td>
<td>1.40 (0.17,11.3)</td>
<td>0.75</td>
<td></td>
</tr>
<tr>
<td>Type A lesion</td>
<td>1.55 (0.34,7.07)</td>
<td>0.57</td>
<td></td>
</tr>
<tr>
<td>Type B1 lesion</td>
<td>0.91 (0.34,2.40)</td>
<td>0.85</td>
<td></td>
</tr>
<tr>
<td>Type B2 lesion</td>
<td>0.77 (0.26,2.28)</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Type C lesion</td>
<td>1.16 (0.31,4.20)</td>
<td>0.83</td>
<td></td>
</tr>
<tr>
<td>Eccentric lesion</td>
<td>0.46 (0.17,1.25)</td>
<td>0.13</td>
<td>0.34</td>
</tr>
<tr>
<td>Ostial location</td>
<td>3.36 (0.19,58.4)</td>
<td>0.43</td>
<td></td>
</tr>
<tr>
<td>Calcified lesion</td>
<td>0.69 (0.19,2.57)</td>
<td>0.58</td>
<td></td>
</tr>
<tr>
<td>Recanalized total occlusion</td>
<td>1.30 (0.16,10.5)</td>
<td>0.81</td>
<td></td>
</tr>
<tr>
<td>Bifurcation lesion</td>
<td>0.16 (0.04,0.69)</td>
<td>0.014</td>
<td>0.002</td>
</tr>
<tr>
<td>Adjunctive balloon PTCA</td>
<td>0.62 (0.10,3.01)</td>
<td>0.43</td>
<td></td>
</tr>
<tr>
<td>Two bends before lesion</td>
<td>0.48 (0.09,0.71)</td>
<td>0.002</td>
<td>0.004</td>
</tr>
<tr>
<td>Calcified long lesion (&gt;10 mm) in vessel ≤3.0 mm</td>
<td>0.79 (0.13,4.58)</td>
<td>0.98</td>
<td></td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>1.01 (0.93,1.09)</td>
<td>0.84</td>
<td></td>
</tr>
<tr>
<td>Lesion &gt;10 mm</td>
<td>1.50 (0.51,4.40)</td>
<td>0.39</td>
<td></td>
</tr>
<tr>
<td>Vessel diameter (mm)</td>
<td>1.35 (0.58,3.19)</td>
<td>0.48</td>
<td></td>
</tr>
<tr>
<td>Pretreatment stenosis (%)</td>
<td>1.04 (0.99,1.10)</td>
<td>0.13</td>
<td>0.03</td>
</tr>
</tbody>
</table>

CI, confidence interval; PTCA, percutaneous transluminal coronary angioplasty.

the 197 patients with clinical follow-up, 61 (31.0%) had clinical evidence of restenosis with recurrence of angina, positive exercise treadmill test, myocardial infarction, or need for revascularization (bypass surgery or repeat angioplasty). No patients died during follow-up. Follow-up angiography was obtained in 152 of 183 patients (83.1%). Of the 152 patients, 58 (38%) had clinical evidence of restenosis. Of the 31 patients who did not return for follow-up angiography, clinical information was available in 29, of whom three (10%) were asymptomatic. Angiographic investigation in 152 patients provided information about restenosis at 164 laser-treated lesions. Angiographic restenosis, defined as >50% stenosis, was seen in 78 of 164 lesions (47.6%) in 72 of 152 patients (47.4%). The mean timing of angiographic follow-up was 5.8±2.1 months (range, 3.2–11.0 months) for patients without angiographic restenosis and 4.5±2.2 months for patients with restenosis (p=0.0011).

Predictors of Clinical Success and Restenosis: Multivariate Analysis

Clinical success rates with excimer laser coronary angioplasty were equivalent for simple and complex lesions: 94.1% for type A lesions, 91.4% for type B1, 89.4% for type B2, and 94.7% for type C lesions. Major complication rates (Q wave or non-Q wave myocardial infarction or need for coronary artery bypass surgery during hospitalization) were not significantly affected by lesion complexity: 5.9% for type A lesions, 6.2% for type B1, 8.5% for type B2, and 2.6% for type C lesions. Logistic regression analysis was performed to identify predictors of clinical success (Table 4). Multivariate analysis of 28 variables showed that bifurcation lesions and tortuous vessels had reduced odds of clinical success. Trends toward decreased success were observed for diabetic patients (OR=0.40, p=0.10), eccentric lesions (OR=0.46, p=0.34), lesions in the right coronary artery (OR=0.29, p=0.06), and calcified lesions (OR=0.69, p=0.58). Clinical success was achieved in 12 of 13 patients with calcified, long (>10 mm) lesions in vessels ≤3.0 mm (OR=0.79, p=0.98). On the other hand, all 16 patients with ostial lesions (OR=3.36, p=0.43) and 14 of 15 patients with lesions in saphenous vein grafts (OR=1.40, p=0.75) were successfully treated.
The multivariate model may account for 23% of the variability in clinical success ($r^2=0.23$, $p=0.0003$), suggesting that the clinical outcome from excimer laser angioplasty, albeit successful in >90% of cases after careful patient selection, is difficult to predict from the variables evaluated.

Logistic regression analysis was used to identify predictors of restenosis after excimer laser angioplasty. Angiographic restenosis was not influenced by lesion complexity, lesion location, history of restenosis after prior balloon angioplasty, or several other clinical and angiographic variables (Table 5). Restenosis was seen in only three of 15 lesions in old (>3 years) saphenous vein grafts, giving reduced odds of restenosis at this site by multivariate analysis (OR=0.18, $p=0.01$).

Adjunctive balloon angioplasty did not increase the risk of restenosis. Instead, adjunctive balloon dilatation showed a trend toward a lower restenosis rate (OR=0.74, $p=0.62$). A borderline reduced odds of restenosis was observed when the postprocedural lumen diameter was $\geq 2.5$ mm (OR=0.32, $p=0.08$). However, the overall multivariate model was limited in predicting restenosis ($r^2=0.04$, $p=0.03$).

**Discussion**

This study shows that excimer laser--facilitated coronary angioplasty produced a 92% clinical success rate in a series of 200 patients with a broad range of coronary artery disease. Despite these results, the role of excimer laser angioplasty for complex coronary artery disease remains uncertain. Relative risk analysis and comparisons with balloon angioplasty may identify indications for the new treatment.

**Comparison of Excimer Laser With Balloon Angioplasty**

Patients will benefit from treatment with excimer laser--facilitated angioplasty if the new technology has higher initial success, fewer complications, or less restenosis than balloon angioplasty. Unfortunately, direct comparisons of excimer laser with balloon angioplasty do not exist. In the absence of a randomized trial, however, certain conclusions may be reached about the new technology if fair comparisons are made. We must be cautious in using balloon angioplasty data from the 1985–1986 NHLBI Registry, which reported a clinical success rate of 78%, because patient selection and balloon angioplasty techniques have improved during the past 5 years. Using the ACC/AHA Task Force success rates for balloon angioplasty should also be avoided because the estimates in the report are based on experienced opinion and not on original data.

Recent studies have analyzed excimer laser and balloon angioplasty results according to lesion complexity. Ellis et al have reported that balloon dilatation of type A lesions has better success rates (92%) than type B1 (84%), type B2 (76%), or type C lesions (61%). Comparing these data with excimer laser results is not ideal because the two treatment groups are neither matched nor concurrent: All patients in the balloon angioplasty study had multivessel disease and were treated before 1988. Furthermore, lumping excimer-treated lesion types together in the ACC/AHA classification is inappropriate because the “ABC” classification pertains to balloon angioplasty treatment and includes several lesions that have not been treated with excimer laser angioplasty (e.g., thrombus, lesion in bend $>90^\circ$). The conclusion that excimer laser coronary angioplasty is suitable for complex lesions requires further definition. Analysis of excimer laser results by lesion type is needed.

**Relative Risk Analysis of Acute Success**

Analysis of acute success rates shows that certain lesion types should not be treated with excimer laser coronary angioplasty. Bifurcation lesions are associated with a decreased likelihood of success because dissection of the tissue between the two side branches cannot
be controlled. Moderately tortuous vessels have decreased success with excimer laser angioplasty but can usually be approached with flexible balloon catheters. Although right coronary artery lesions have decreased success on univariate analysis (a problem that may be due to vessel tortuosity), multivariate analysis did not identify vessel location as an independent predictor of acute clinical success. Eccentric lesions are associated with a trend toward reduced likelihood of success, probably because no directional capability is currently available for laser ablation. Calcified stenoses have a nonsignificant trend toward lower clinical success than noncalcified stenoses with excimer laser treatment. Calcified lesions are significantly more difficult than noncalcified stenoses to treat with balloon angioplasty (90% versus 82%, p = 0.01).

Analysis by Lesion Type

We have observed that excimer laser–facilitated angioplasty has >90% success rates with certain lesions that are difficult to treat with balloon angioplasty. In this study, we observed that excimer laser angioplasty succeeded in 93% of diffuse lesions (>20 mm), a rate that compares favorably with the 82% success rate for balloon angioplasty in such lesions. Excimer laser–facilitated angioplasty produced clinical success in 94% of saphenous vein grafts more than 3 years old, which may be superior to that for balloon angioplasty alone (death, 4%; myocardial infarction, 13%; emergency bypass, 4%). The success rate with excimer laser angioplasty for ostial lesions (16 of 16) appears to be superior to balloon angioplasty, which yields successful results in 74% to 79% of cases.

Restenosis

The angiographic restenosis rate of 48% that we observed after excimer laser–facilitated angioplasty is similar to the 40–49% restenosis rates recently reported for balloon angioplasty. Thus, there is no evidence to suggest that excimer laser has a lower overall restenosis rate than balloon angioplasty. In contrast to balloon angioplasty, however, excimer laser–facilitated angioplasty has a lower restenosis rate in saphenous vein grafts than in native vessels.

Restenosis after excimer laser–facilitated coronary angioplasty may be due to ascertainment bias, patient selection, or inadequate ablation of tissue. Symptomatic patients are more likely than asymptomatic patients to comply with the protocol requirement of a 6-month follow-up angiogram. Using the model of Califf et al. and an estimated restenosis rate of 18% in asymptomatic patients who did not return for angiography, we would expect an angiographic restenosis rate of 42% if complete angiographic follow-up had been achieved. Patient selection may influence restenosis rates. We selected many patients for treatment with excimer laser coronary angioplasty because of the increased risk of restenosis reported after balloon angioplasty in the proximal left anterior descending coronary artery, in saphenous vein grafts, or after multiple restenosis events from prior angioplasty. Restenosis may be caused by inadequate tissue ablation despite the ability of excimer laser energy at 308 nm to vaporize atheromatous plaque; it may be caused by mechanical dilatation, because only a fraction of the catheter tip is composed of optical fibers; or it may be caused by deep arterial injury, which cannot always be avoided during excimer laser coronary angioplasty, as shown by the 14.5% incidence of dissection and 2.0% incidence of perforation. The mechanisms of inadequate tissue removal and deep arterial injury probably contribute to the similar restenosis rates after directional atherectomy.

In this study, we observed that adjunctive balloon angioplasty did not increase the likelihood of restenosis compared with the use of excimer laser alone. This finding is in contrast to the conclusion of another study in which statistical significance was neither presented nor probably reached. None of the determinants of restenosis after balloon angioplasty, including lesion location or restenosis after prior angioplasty, predicted restenosis after excimer laser coronary angioplasty. The analysis presented here shows a trend toward a lower restenosis rate when the postprocedure lumen diameter is ≥2.5 mm. However, the number of observations is small and the confidence limits are correspondingly large.

Balloon Dilatation Failure

The third criterion for success of excimer laser coronary angioplasty deals with the indication of balloon dilatation failures. Because only anecdotal experience has been reported here (Figure 1) and in another case report, no firm conclusions about the usefulness of excimer laser coronary angioplasty for this indication can be made.

Study Limitations

This is not a randomized comparison of excimer laser with balloon angioplasty; instead, we used relative risk analysis and comparisons with balloon angioplasty to identify where excimer laser angioplasty shows promise and where it should be avoided. The analysis is helpful in identifying high-risk lesions. However, the analysis is limited by the small number of statistically significant predictors in the cohort of 200 patients. Statistical power can be expected to increase with larger numbers of patients in a manner that depends on the square root of the number of patients. Other limitations of the study include incomplete angiographic follow-up, which is available for 83.1% of the patients. Fortunately, we have obtained clinical follow-up in 98.5% of patients and observed that 26 of the 29 patients who did not undergo follow-up angiography were asymptomatic. It is therefore unlikely that the angiographic restenosis rates are being underreported in this study. Other limitations of this study include the use of quantitative angiography in only a subgroup of patients. Basing the selection of patients for quantitative angiography on the suitability of adequate films ensured that the subgroup of patients was representative of the overall population. The quantitative angiography was useful to show that visual assessment is accurate after laser dilatation, after balloon angioplasty, and at follow-up. Another limitation is that a core angiography laboratory has not been used. Instead, two different quantitative angiography systems have been used. However, both systems have been previously validated, and it is unlikely that quantitative analysis for all patients would alter the conclusions of the study.
Summary

Excimer laser–facilitated coronary angioplasty shows promise for lesions that are long, ostial in position, or located in degenerated saphenous vein grafts. To establish excimer laser coronary angioplasty as a useful adjunct to balloon angioplasty, a randomized trial must be conducted to compare the acute success of excimer laser–facilitated treatment with balloon angioplasty alone for selected lesion types.

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