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Predictors of outcome of percutaneous excimer laser coronary angioplasty of saphenous vein bypass graft lesions. The Percutaneous Excimer Laser Coronary Angioplasty Registry.

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Predictors of Outcome of Percutaneous Excimer Laser Coronary Angioplasty of Saphenous Vein Bypass Graft Lesions*

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A total of 495 patients underwent treatment with excimer laser angioplasty for 545 saphenous vein graft stenoses. Clinical success was achieved in 485 of 495 patients (92%), as indicated by >50% residual stenosis at every target lesion and no complication during hospitalization. At least 1 in-hospital complication occurred in 30 of 495 patients (6.1%); death (1.0%), bypass surgery (0.8%), and Q-wave (2.4%) or non-Q-wave (2.2%) myocardial infarction. Relative risk analysis showed that ostial lesions (n = 65) tended to have higher clinical success (success rate = 95%, adjusted odds ratio [OR] = 2.1 [95% confidence interval (CI) 0.62, 6.88]; p = 0.24) and lower complications (complication rate = 0%, OR = 0.30 [CI 0.01, 0.79]; p = 0.03) than lesions in the body of the vein graft. Lesions >10 mm (n = 131) had lower success (success rate = 84%, OR = 0.30 [CI 0.16, 0.56]; p = 0.001) and higher complications (complication rate = 12%, OR = 3.3 [CI 1.6, 6.6]; p = 0.004) than discrete lesions. Lesions in small vein grafts <3.0 mm (n = 76) tended to have increased success (success rate = 94%, OR = 1.55 [CI 0.70, 3.44]; p = 0.39) and lower complications (complication rate = 2.2%, OR = 0.31 [CI 0.10, 0.94]; p = 0.03). Thus, excimer laser-facilitated angioplasty has the most favorable outcome for discrete lesions located at the ostium of all grafts and in the body of smaller saphenous vein grafts. Comparison of excimer laser angioplasty with other treatments for these types of saphenous vein graft lesions is required to establish the clinical usefulness of excimer laser treatment.

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Angioplasty of saphenous vein graft lesions remains a significant challenge. Embolization of thrombus or atheromatous material occurs in 2% to 17% of patients, and restenosis at the treated site appears in 30% to 80%.

Methods

Patient enrollment: Between May 8, 1989, and February 28, 1993, a total of 495 patients had 545 lesions in saphenous vein grafts treated with excimer laser angioplasty in the Percutaneous Excimer Laser Coronary Angioplasty Registry (see Appendix). Patients were not considered for excimer laser angioplasty if they had a filling defect in the vein graft selected for treatment with excimer laser angioplasty, except in 8 cases reported elsewhere, or if the lesion existed in the angulated anastomotic site. All patients were requested to return for 6-month angiographic follow-up. All patients gave informed consent to participate in the protocol, which was approved by both the Food and Drug Administration and the institutional review boards of the participating hospitals.

Excimer laser angioplasty: All patients were treated with the CVX-300<sup>®</sup> excimer laser (Spectranetics Corporation, Colorado Springs, Colorado), using over-the-wire catheters with diameters of 1.4, 1.7, or 2.0 mm and techniques previously described.

Definitions: Distal embolization was defined by filling defects distal to the treated graft, with or without evidence of "no-reflow." (Creatine kinase measurements were required only for patients with new electrocardiographic changes or ischemic chest pain lasting >30 minutes.) Angiographic restenosis was defined by the presence of >50% stenosis at the treated site. Graft perforation was defined by a persistent extravascular collection of contrast medium beyond the graft wall with a well-defined exit port. An ostial lesion was defined as a stenosis positioned within 2 mm of the origin of the graft. An ulcerated lesion was defined by the appearance of an abrupt face, scalloped edge, or irregular border. Lesion length was measured with calipers, using catheter...
calibration to account for magnification, and defined as the distance from the proximal to the distal shoulder spanning ≥50% stenosis in a nonforeshortened projection. **Graft diameter** was measured with calipers, using the guide catheter centered in the frame as calibration reference.

**Statistical analysis:** Logistic regression analysis identified predictors of clinical success or major complications from the following variables: graft size, lesion length, or lesion morphology. Odds ratios were calculated to give the likelihood that patients with a given variable had increased or decreased likelihood of an outcome, as compared with all other patients without the variable.\(^1\) Adjusted odds ratios with 95% confidence intervals for clinical success and restenosis were calculated according to the method of Woolf.\(^2\) All statistical analyses were performed with a standard statistical package (SAS, Cary, North Carolina). Variables found to have borderline significance on univariable analysis (p ≤0.10) were included in the multivariable logistic regression analysis.\(^3\) All quantitative data are presented as mean ± SD.

**RESULTS**

Patients and saphenous vein graft lesions: Excimer laser coronary angioplasty was performed in 495 patients with 545 saphenous vein graft lesions. The average age of the patients was 63 ± 11 years. In all, 381 patients (77%) were men, 332 patients (67%) had unstable angina, and 104 patients (21%) had diabetes mellitus.

The mean graft age was 8.0 ± 2.0 years, and 52% of the lesions were eccentric, 24% were >10 mm in length, 15% were ulcerated, and 12% involved the graft ostium. The mean graft diameter for all patients was 3.2 ± 0.7 mm, whereas the mean graft diameter for those receiving laser-alone treatment was 3.1 ± 0.7 mm (p = NS). Adjunctive treatment included balloon angioplasty at 496 (91%), directional atherectomy at 2 (0.4%), and stent implantation at 0 of the 545 treated sites (Table I). For all patients, the mean diameter stenosis was reduced from 88 ± 13% before treatment to 45 ± 21% after laser, and then to 20 ± 16% at the end of the procedure with adjunctive therapy.

**Success:** Clinical success was achieved in 455 of 495 patients (92%), as defined by ≤50% stenosis at every target lesion and no major complication at any time during hospitalization (death, Q-wave or non-Q-wave myocardial infarction, abrupt vessel closure, repeat percutaneous transluminal coronary angioplasty, or need for bypass surgery). Logistic regression analysis showed that clinical success was influenced by lesion type (Figure 1). Ostial lesions tended to have increased success (success rate = 95%, adjusted odds ratio [OR] = 2.1 [95% confidence interval (CI) range 0.62, 6.88]; p = 0.24), whereas lesions >10 mm in length had reduced success (success rate = 84%, OR = 0.30 [CI 0.16, 0.56]; p = 0.001). Neither graft age (p = 0.76) nor laser catheter size (p = 0.75) was found to be a predictor of clinical success.

**Complications (Table II):** At least 1 complication occurred in 30 of 495 patients (6.1%). Five patients died during hospitalization (1.0%), 3 patients were referred to coronary artery bypass graft surgery; MI = myocardial infarction.

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**TABLE I Description of 545 Stenoses**

<table>
<thead>
<tr>
<th>Variable</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eccentric (%)</td>
<td>25.1  (52)</td>
</tr>
<tr>
<td>Length &gt;10 mm (%)</td>
<td>13.1  (24)</td>
</tr>
<tr>
<td>Restenosis (%)</td>
<td>13.1  (16)</td>
</tr>
<tr>
<td>Ulcerated (%)</td>
<td>13.1  (15)</td>
</tr>
<tr>
<td>Ostial (%)</td>
<td>65.0  (12)</td>
</tr>
<tr>
<td>Adjunctive balloon angioplasty (%)</td>
<td>49.6  (91)</td>
</tr>
<tr>
<td>Adjunctive directional atherectomy (%)</td>
<td>2.0  (0.4)</td>
</tr>
<tr>
<td>Adjunctive graft stenting (%)</td>
<td>0.0   (0.0)</td>
</tr>
<tr>
<td>Mean graft age (years)</td>
<td>8.0 ± 2.0</td>
</tr>
</tbody>
</table>

**TABLE II Complications**

<table>
<thead>
<tr>
<th>Complications in 495 patients (%)</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death during hospitalization</td>
<td>5.1  (1.0)</td>
</tr>
<tr>
<td>CABG during hospitalization</td>
<td>3.1  (0.6)</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>12.2 (2.4)</td>
</tr>
<tr>
<td>Non-Q-wave MI</td>
<td>11.1 (2.2)</td>
</tr>
<tr>
<td>Complications for 545 stenoses (%)</td>
<td></td>
</tr>
<tr>
<td>Dissection</td>
<td>48.8</td>
</tr>
<tr>
<td>Abrupt closure</td>
<td>22.4</td>
</tr>
<tr>
<td>Embolization</td>
<td>18.3</td>
</tr>
<tr>
<td>Perforation (minor contrast extravasation only)</td>
<td>7.1</td>
</tr>
<tr>
<td>Perforation with clinical complication</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**15%** were ulcerated, and **12%** involved the graft ostium. The mean graft diameter for all patients was 3.2 ± 0.7 mm, whereas the mean graft diameter for those receiving laser-alone treatment was 3.1 ± 0.7 mm (p = NS). Adjunctive treatment included balloon angioplasty at 496 (91%), directional atherectomy at 2 (0.4%), and stent implantation at 0 of the 545 treated sites (Table I). For all patients, the mean diameter stenosis was reduced from 88 ± 13% before treatment to 45 ± 21% after laser, and then to 20 ± 16% at the end of the procedure with adjunctive therapy. 

**SUCCESS:** Clinical success was achieved in 455 of 495 patients (92%), as defined by ≤50% stenosis at every target lesion and no major complication at any time during hospitalization (death, Q-wave or non-Q-wave myocardial infarction, abrupt vessel closure, repeat percutaneous transluminal coronary angioplasty, or need for bypass surgery). Logistic regression analysis showed that clinical success was influenced by lesion type (Figure 1). Ostial lesions tended to have increased success (success rate = 95%, adjusted odds ratio [OR] = 2.1 [95% confidence interval (CI) range 0.62, 6.88]; p = 0.24), whereas lesions >10 mm in length had reduced success (success rate = 84%, OR = 0.30 [CI 0.16, 0.56]; p = 0.001). Neither graft age (p = 0.76) nor laser catheter size (p = 0.75) was found to be a predictor of clinical success.

**Complications (Table II):** At least 1 complication occurred in 30 of 495 patients (6.1%). Five patients died during hospitalization (1.0%), 3 patients were referred for coronary artery bypass graft surgery; MI = myocardial infarction.

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**FIGURE 1.** Odds ratios and 95% confidence intervals are presented to identify predictors of clinical success in 495 patients with 545 saphenous vein graft lesions. By logistic regression analysis, variables with an odds ratio significantly <1.0 are associated with decreased likelihood of clinical success. >10 mm = lesion length. PTCA = percutaneous transluminal coronary angioplasty.
for repeat bypass surgery (0.6%), 12 patients experienced Q-wave myocardial infarction (2.4%), and 11 patients had non-Q-wave myocardial infarction (2.2%). Eighteen of 545 lesions were associated with embolization (3.3%). Twenty-two lesions were associated with abrupt closure (4.0%). Seven treated sites were associated with graft perforation (1.3%), which was manifest in every case as minor extravasation of contrast medium and successfully sealed with balloon angioplasty without sequelae. No patient experiencing perforation died or required pericardiocentesis or emergency surgery. Major complications from excimer laser angioplasty (death, myocardial infarction, or bypass surgery) were influenced by lesion type (Figure 2). Multivariable logistic regression analysis showed lower likelihood of complications for ostial lesions (complication rate = 0%, OR = 0.10 [CI 0.01, 0.79]; p = 0.03), restenosis lesions (complication rate = 1.2%, OR = 0.24 [CI 0.05, 1.23]; p = 0.07), and lesions in smaller grafts <3.0 mm (complication rate = 2.2%, OR = 0.31 [CI 0.10, 0.94]; p = 0.03). An increased likelihood of complications was seen for lesions >10 mm in length (complication rate = 12%, OR = 3.3 [CI 1.6, 6.6]; p = 0.004). Neither graft age (p = 0.19) nor laser catheter size (p = 0.47) was found to be a predictor of major complications.

Angiographic restenosis: Six-month angiographic follow-up was obtained in 161 of 364 eligible patients (44%). Of the patients with angiographic follow-up, >50% stenosis was seen at 1 or more of the treated sites in 88 patients (55%). Restenosis occurred less often in large grafts ≥3.0 mm (restenosis rate = 50%, adjusted OR = 0.51 [CI 0.25, 1.01]; p = 0.06) than in smaller grafts (Figure 3). Small grafts with lesions >10 mm had restenosis rates of 70%.

DISCUSSION

Atheromatous disease in saphenous vein grafts is histologically similar to that found in native coronary arteries, and consists of fibrointimal hyperplasia, atherosclerosis, and thrombus either alone or in combination. The accumulation of foam cells and the formation of irregular fibrous caps increase the likelihood of erosion, rupture, and thrombus formation. Because specific angiographic characteristics of lesions influence the outcome after interventional procedures in native vessels, it is reasonable to propose that angiographic morphology influences outcome after excimer laser treatment of saphenous vein graft lesions.

In this study, we observed that a wide range of saphenous vein graft lesions can be treated with excimer laser

![Variable](image1)

![Graph](image2)

![Graph](image3)
angioplasty with an overall success rate of 92%. Lesion morphology and graft dimensions, however, did influence the procedural outcome. We observed that success and complication rates were superior when excimer laser angioplasty was used for ostial lesions of all vein grafts and for discrete stenoses in vein grafts <3.0 mm. After controlling for lesion and graft morphology, we observed no effect of graft age on outcome after excimer laser angioplasty, a finding that differs from the results reported for balloon angioplasty. Using balloon angioplasty for saphenous vein graft lesions, Webb and colleagues achieved clinical success in 119 of 140 patients (85%), which was higher for younger grafts <1 year of age (92%) but lower for proximal sites (80%). Platko and co-workers reported that balloon angioplasty of 48 grafts > 3 years of age (mean age of 7.5) had complication rates (4% risk of death, 15% risk of embolization, and 4% risk of bypass surgery) that were significantly higher than those for younger grafts. Dorros et al achieved clinical success with balloon angioplasty in 44 of 53 saphenous vein graft lesions (83%), and observed embolization in 6%. Reeves et al observed clinical success with balloon angioplasty in 47 of 57 patients (82%), and observed evidence of embolization in 11 of 64 grafts (17%). In this study, we observed a 1% risk of death, 3% risk of embolization, and 0.6% risk of bypass surgery for excimer laser treatment of lesions in saphenous vein grafts with a mean age of 8.0 years.

Treatment of saphenous vein graft lesions with directional atherectomy has been associated with embolization in 8 of 91 lesions (9%) and restenosis rates of 53% to 82% for primary and recurrent restenosis lesions. Treatment of saphenous vein graft lesions with transluminal extraction atherectomy has been associated with success in 23 of 29 lesions (79%), but distal embolization occurred in 5 of 22 degenerated grafts (23%). In this study, we observed better success rates for smaller grafts than larger grafts with excimer laser angioplasty, a finding that has also been reported for balloon angioplasty. On the other hand, smaller grafts have not been found to be suitable for endoluminal stenting, a therapy that has been reported, however, to have very good success (96%) and complication (2%) rates in large grafts. Thus, excimer laser angioplasty or balloon angioplasty may complement endoluminal stenting by allowing lesions in a broad range of graft sizes to be treated with various interventional methods.

The current study has a number of limitations. Although each investigator reported all clinical and angiographic results to a core clinical data facility, no core angiographic laboratory was available for analysis of cineangiograms. To ensure uniform reporting, all investigators agreed prospectively on a set of definitions for the morphologic classification of saphenous vein graft lesions. Second, angiographic follow-up was very low at 44% compliance rate. Thus, restenosis rates reported here are inaccurate. However, it is unlikely that the restenosis rates are overrepresented in this report, because symptomatic patients were more likely to comply with the request for 6-month angiographic follow-up than asymptomatic patients. Also, serial creatine kinase measurements were not obtained in asymptomatic patients. Thus, the incidence of silent distal embolization is underestimated by this study.

In conclusion, this study suggests that excimer laser angioplasty can be best used to treat discrete lesions at the ostium of all vein grafts or in the body of smaller saphenous vein grafts. Direct comparison with other interventional methods is required to define the ultimate clinical use of excimer laser angioplasty in saphenous vein graft lesions.

APPENDIX

Centers and investigators for the Percutaneous Excimer Laser Coronary Angioplasty Registry: Alabama Heart Institute, Birmingham, Alabama (E. Cohen); Arizona Heart Institute, Phoenix, Arizona (R. M. Siegel); Brigham and Women's Hospital, Boston, Massachusetts (J. A. Bittl); Cornell New York Hospital, New York, New York (T. A. Sanborn); Crawford Long Hospital, Atlanta, Georgia (D. C. Morris); Duke University Medical Center, Durham, North Carolina (J. E. Tcheng, H. R. Phillips); George Washington University Medical Center, Washington, D.C. (J. Segal); Good Samaritan Hospital, Phoenix, Arizona (N. Lauffer); Gunderson Clinic, La Crosse, Wisconsin (J. Bird, R. Green); Memorial Hospital, Colorado Springs, Colorado (C. Kucinski, R. Blonder); Methodist Hospital, Lubbock, Texas (P. Walter, P. Overlie); Mills-Peninsula Hospital, Palo Alto, California (R. Ginsburg); Mt. Sinai Medical Center, Miami Beach, Florida (P. S. Swaye, P. Vignola); New England Deaconess Hospital, Boston, Massachusetts (G. S. Abela); Northwestern Memorial Hospital, Chicago, Illinois (B. Kramer); Penrose-St. Francis Hospital, Colorado Springs, Colorado (J. Kleiner, R. Moothart); Scott & White Clinic, Temple, Texas (L. Watson); Southeast Missouri Hospital, Cape Girardeau, Missouri (C. R. Talbert, J. Chapman); St. Elizabeth's Hospital, Boston, Massachusetts (J. M. Isner); St. Francis Hospital, Roslyn, New York (R. Hershman); St. Francis Medical Center, Pittsburgh, Pennsylvania (J. Power); Tampa General Hospital, Tampa, Florida (S. K. Chokshi); Texas Heart Institute (M. Schnec, R. Leachman); University of California, Irvine Medical Center, Irvine, California (J. Tobis); University of Iowa, Iowa City, Iowa (M. Winniford); University of Michigan Hospital, Ann Arbor, Michigan (S. G. Ellis).

7. Bittl JA, Sanborn TA, Tcheng JE, Siegel RM, Ellis SG. Clinical success, com-