Increased Coronary Perforation in the New Device Era
Incidence, Classification, Management, and Outcome

Stephen G. Ellis, MD; Steven Ajluni, MD; Anita Z. Arnold, DO; Jeffrey J. Popma, MD;
John A. Bittl, MD; Neal L. Eigler, MD; Michael J. Cowley, MD; Russell E. Raymond, DO;
Robert D. Safian, MD; Patrick L. Whitlow, MD

Background The incidence of coronary perforation using new percutaneous revascularization techniques may be increased compared with PTCA. Still, perforation is uncommonly reported, and the optimal management and expected outcome remain unknown. The objectives of the study were to determine the incidence of coronary perforation using balloon angioplasty (percutaneous transluminal coronary angioplasty, PTCA) and new revascularization techniques and to develop optimal strategies for its management based on classification and outcome.

Methods and Results Eleven sites with frequent use of new revascularization devices and prospective coding of consecutive procedures for coronary perforation during 1990 to 1991 contributed to a perforation registry. Patients with perforation were matched by device with an equal-sized cohort without perforation. Data were collected centrally, and all procedural cineangiograms were reviewed at a core angiographic laboratory. A classification scheme based on angiographic appearance of the perforation (I, extraluminal crater without extravasation; II, pericardial or myocardial blushing; III, perforation ≥1-mm diameter with contrast streaming; and cavity spilling) was evaluated as a predictor of outcome and as a basis for management. Perforation was observed in 62 of 12 900 procedures reported (0.5%; 95% confidence interval, 0.4% to 0.6%), more commonly with devices intended to remove or ablate tissue (atherectomy, laser) than with PTCA (1.3%, 0.9% to 1.6% versus 0.1%, 0.1% to 0.1%; P < .001). The perforation population was notable for its advanced age (67 ± 10 years) and high incidence of female sex (46%) (both P < .001 compared with patients without perforation). Perforation could be treated expectantly or with PTCA but without cardiac surgery in 85%, 90%, and 44% of class I, II, and III perforations, respectively. Class I perforations (n = 13, 21%) were associated with death in none, myocardial infarction in none, and tamponade in 8%. The incidences of these adverse events were 0%, 14%, and 13% in class II perforations (n = 31, 50%) and 19%, 50%, and 63% in non–cavity spilling class III perforations, respectively (n = 16, 26%). Two of the 15 instances of cardiac tamponade (13%) were delayed, occurring within 24 hours after dismissal from the catheterization laboratory.

Conclusions The incidence of perforation, while low, is increased with new devices. Women and the elderly are at highest risk. The clinical risk after perforation can be classified angiographically, but even low-risk perforations occasionally have poor clinical outcome. Patients should be observed for delayed cardiac tamponade for at least 24 hours. (Circulation. 1994;90:2725-2730.)

Key Words • angioplasty • revascularization • surgery

Coronary perforation with percutaneous transluminal coronary angioplasty (PTCA) occurs only very rarely.1–5 However, with the recent availability of alternative devices that cut, tear, or ablate in order to improve luminal dimensions, perforations have been noted more frequently.6–8

The purpose of this registry is to gain information about the frequency of perforation during coronary intervention in the 1990s and to collect information to facilitate a rationale management of this problem.

Methods

Patient Population

Patients from 11 contributing institutions (see “Appendix”) where there exists systematic evaluation of the presence of coronary perforation after coronary intervention with at least one interventional device (balloon angioplasty, directional atherectomy [Devices for Vascular Intervention], excimer laser [Advanced Interventional Systems, Inc or Spectranetics Corporation], rotational atherectomy [Heart Technology, Inc], or transluminal extraction atherectomy [Interventional Technology] treated from January 1, 1990, through December 31, 1991, were studied. Clinical data and cineangiograms were requested for all patients with suspected perforation and were evaluated at a central core angiographic and analytic laboratory at the Cleveland Clinic Foundation using standardized data collection forms. Each patient found to have a perforation (index patient) was then matched with the patient having been treated with the same device immediately before the index patient at the same institution, and the matched patients were evaluated in the same manner as the index patients.

Procedural Techniques

The techniques used for application of the devices evaluated in this study have been described in detail elsewhere.6,9–12 Because it was not the purpose of this study to evaluate specific correlates of perforation for each device, limited procedural details were evaluated: device to artery ratio, fluence (for laser treatment), and number of passes across the lesion with the device.

Baseline Clinical Variables

The following baseline clinical variables were obtained from the contributing centers: age, sex, and treatment indication

Received April 11, 1994; revision accepted July 26, 1994.
From The Cleveland Clinic Foundation (S.G.E., A.Z.A., R.E.R., P.I.W.), Cleveland, Ohio; William Beaumont Hospital (S.A., R.D.S.), Royal Oak, Mich; Washington Hospita l Center (J.J.P.), Washington, DC; Brigham and Women's Hospital (J.A.B.), Boston, Mass; Cedars Sinai Medical Center (N.L.E.), Los Angeles, Calif; and Medical College of Virginia (M.J.C.), Richmond, Va.

Correspondence to Stephen G. Ellis, MD, The Cleveland Clinic Foundation, 9500 Euclid Ave, F-25, Cleveland, OH 44195.
© 1994 American Heart Association, Inc.
Angiographic Analysis

All cineangiograms were reviewed at a core angiographic laboratory using previously described techniques including caliper measurement of magnified images with catheter reference calibration. The following variables were noted: cavity spilling (CS) (contrast flow from the site of perforation into a cardiac chamber or cavity, such as the left ventricle or coronary sinus, as opposed to into the pericardium or myocardium), device to artery ratio, modified American College of Cardiology/American Heart Association lesion classification, multivessel disease (>50% diameter stenosis in bypassable vessels in two or more of three epicardial coronary territories), perforation type (prospectively defined as type I, a crater extending outside of the lumen only and in the absence of linear staining angiographically suggestive of a dissection [Fig 1]; type II, pericardial or myocardial blush without a ≥1-mm exit hole; and type III, frank streaming of contrast through a ≥1-mm exit hole [Fig 2 and Table 1]), pretreatment percent diameter stenosis, posttreatment percent diameter stenosis, Thrombolysis in Myocardial Infarctio flow grade after treatment, and vessel site treated.

Clinical Outcome Variables

The following variables describing in-hospital outcome were obtained from the contributing centers: cardiac tamponade, death, elective coronary artery bypass surgery, duration of balloon inflation (when angioplasty was used as treatment for the perforation), emergency coronary artery bypass surgery, myocardial infarction (creatine kinase ≥2 upper limit of normal with MB fraction >5%), maximum creatine kinase level after treatment, Q-wave myocardial infarction, and treatment of the perforation with balloon angioplasty.

Statistical Analysis

All data were entered into the Perforation Registry Database at the Cleveland Clinic Foundation. Data are expressed as mean±1 SD unless otherwise indicated. For comparison of paired data, dependent t test analyses were used. For nonpaired data, χ² analyses were used to test differences in categorical variables, and ANOVA techniques were used to test differences in continuous variables. Analyses were performed using SYSTAT software (System for Statistics, version 5.01, 1990).
Results

Incidence of Perforation

The incidence and classification of perforations for each device are enumerated in Table 2. Although differences in patients treated and in device operators make device comparisons somewhat difficult to interpret, it appears that laser ablation and rotational or extraction atherectomies have a somewhat higher incidence of perforation than does directional atherectomy and that all have a greater incidence than is seen with balloon angioplasty.

Baseline Demographics

Clinical characteristics of the patients with and without perforation are shown in Table 3. Women and the elderly appeared to be at considerably higher risk of perforation ($P<.001$).

Device Sizing

The device to artery ratios for patients with and without perforation are enumerated by device in Table 4. For each device, the number of patients is small, hence increasing the likelihood of a type II statistical error. A general trend for increased risk with larger devices could not be demonstrated except specifically for balloon angioplasty (1.19±0.17 versus 0.92±0.16, $P=.03$).

Outcome After Perforation

In-hospital clinical outcomes after treatment, separated by perforation classification, are displayed in Table 5. Only a little more than 60% of type I perforations were treated with further balloon dilatation, and with the exception of one perforation that was clinically silent until the patient developed cardiac tamponade 24 hours later, none were associated with clinical events. The vast majority of type II perforations were treated with balloon dilatation (median duration, 13 minutes), but adverse sequelae were infrequent. Heparin therapy was maintained in these patients. Type III perforations, however, were associated with a very high incidence of major adverse events (death, 19%; emergency bypass surgery, 19%).
surgery, 63%; Q-wave myocardial infarction, 15%; cardia
tamponade, 63%) despite treatment with pro-
longed balloon inflation (median duration, 34 minutes).
One delayed (6 hours) tamponade occurred in this
group also.

Discussion
Coronary perforation during balloon angioplasty oc-
curs very infrequently, and when it does, it usually
results from guide wire trauma, balloon rupture, or
balloon oversizing.1-5 As experience accrues with a
number of devices designed to overcome some of the
limitations of PTCA that cut, abrade, or ablate tissue, it
appears that these may be associated with a higher
incidence of this complication,6-8 although the clinical
question has not been studied systematically. This
increased incidence of perforation is perhaps not surpris-
ding due to their limited capacity for directional guidance
and tissue removing as opposed to displacing the mecha-
nism of action.

In this multicenter report, we collected information
from procedures performed on almost 13,000 patients
during 1990 to 1991 from centers using a variety of new
devices and that prospectively recorded the occurrence
of coronary perforation. The incidence of angiographi-
cally apparent perforation by device ranged from 0.1%
to 2.1% and was appreciably greater with devices that
remove rather than displace tissue (P<.0001). Further-
more, we prospectively tested a classification scheme
(Table 1) designed to predict the likelihood of major
complications and thus assist the interventionalist in
determining the expediency of coronary bypass surgery
and the duration during which the patient with a
perforation is at risk of abruptly developing cardiac
tamponade.

Class I (fully contained) perforations rarely devel-
oped tamponade or resulted in ischemia. These may be
very difficult or impossible to distinguish angiographi-
cally from localized dissections.

Class II (limited extravasation) perforations, when
treated with prolonged balloon inflation, usually have a
lesening of contrast extravasation and so treated also
have a low incidence of adverse sequelae. In both class
I and II perforations, antiocoagulation with aspirin and

TABLE 2. Overall Incidence and Classification of Coronary Perforations

<table>
<thead>
<tr>
<th>Device</th>
<th>Incidence (95% Confidence Interval)</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon angioplasty</td>
<td>14/9080 (0.1%; 0.1-0.1%)</td>
<td>3</td>
</tr>
<tr>
<td>Directional atherectomy</td>
<td>12/1715 (0.7%; 0.7-0.7%)</td>
<td>3</td>
</tr>
<tr>
<td>Excimer laser-I</td>
<td>10/529 (1.9%; 0.8-3.0%)</td>
<td>3</td>
</tr>
<tr>
<td>Excimer laser-II</td>
<td>7/371 (1.9%; 0.5-3.3%)</td>
<td>0</td>
</tr>
<tr>
<td>Rotablator</td>
<td>10/771 (1.3%; 0.5-2.1%)</td>
<td>3</td>
</tr>
<tr>
<td>TEC</td>
<td>9/434 (2.1%; 0.8-3.4%)</td>
<td>1</td>
</tr>
</tbody>
</table>

CS indicates cavity spilling; TEC, transluminal extraction catheter.

TABLE 3. Clinical Characteristics of Patients With and Without Perforation (Matched Analysis)

<table>
<thead>
<tr>
<th></th>
<th>Perforation (n=62)</th>
<th>No Perforation (n=62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>67±10</td>
<td>58±18*</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>54</td>
<td>84*</td>
</tr>
<tr>
<td>Multivessel, %</td>
<td>79</td>
<td>66</td>
</tr>
<tr>
<td>Treatment indication, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTCA-induced dissection</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Stable angina</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>48</td>
<td>56</td>
</tr>
<tr>
<td>Vessel site, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left main</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Proximal LAD</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td>Mid/distal LAD</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>Proximal LCx</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Mid/distal LCx</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Proximal RCA</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Mid/distal RCA</td>
<td>19</td>
<td>11</td>
</tr>
<tr>
<td>Saphenous vein graft</td>
<td>19</td>
<td>23</td>
</tr>
<tr>
<td>Internal mammary artery graft</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Pretreatment % stenosis</td>
<td>76±15</td>
<td>75±13</td>
</tr>
<tr>
<td>Pretreatment morph. %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>B1</td>
<td>44</td>
<td>40</td>
</tr>
<tr>
<td>B2</td>
<td>31</td>
<td>29</td>
</tr>
<tr>
<td>C</td>
<td>12</td>
<td>11</td>
</tr>
</tbody>
</table>

PTCA indicates percutaneous transluminal coronary angioplasty; LAD, left anterior descending coronary artery; LCx, left circumflex artery; and RCA, right coronary artery.

*P<.001.

TABLE 4. Influence of Device to Artery Ratio on Risk of Perforation

<table>
<thead>
<tr>
<th></th>
<th>Perforation (n=62)</th>
<th>No Perforation (n=62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon angioplasty</td>
<td>1.19±0.17</td>
<td>0.92±0.16*</td>
</tr>
<tr>
<td>Directional atherectomy</td>
<td>0.73±0.14</td>
<td>0.73±0.08</td>
</tr>
<tr>
<td>Excimer laser-I</td>
<td>0.65±0.12</td>
<td>0.66±0.18</td>
</tr>
<tr>
<td>Excimer laser-II</td>
<td>0.64±0.16</td>
<td>0.43±0.10</td>
</tr>
<tr>
<td>Rotablator</td>
<td>0.60±0.13</td>
<td>0.72±0.17</td>
</tr>
<tr>
<td>TEC</td>
<td>0.76±0.36</td>
<td>0.61±0.11</td>
</tr>
</tbody>
</table>

TEC indicates transluminal extraction catheter.

*P=.03.
heparin can be maintained. Importantly, however, there does appear to be a low (<5% to 10%) incidence of delayed (up to 24 hours at least) tamponade, arguing for careful patient monitoring for at least that time period.

Class III (brisk extravasation) perforations were, however, associated with a high incidence of dramatic complications including abrupt tamponade, need for urgent bypass surgery, and a disturbingly high mortality. Appropriate management would appear to include immediate placement of a perfusion balloon (if such a balloon can be placed very rapidly) to minimize ischemia and because some perforations can be "sealed." Expectant therapy carries with it a risk of delayed tamponade, however, and it may well be that all but the highest risk surgical candidates should be referred for bypass surgery. Certainly, most patients will require surgery, and many develop tamponade before any balloon can be placed over the leak. We did note, however, that the few class III perforations with contrast spilling directly into either the left ventricle or coronary sinus did not have such catastrophic consequences; hence, the terminology "CS," referring to cavity spilling and a somewhat more benign presentation, was developed in a post hoc manner.

Conclusions

The conclusions of this study should be viewed in the context of several study limitations. First, as a multicenter, retrospective study, not all the procedural details one might like to have (eg, details regarding the degree of postprocedural anticoagulation in relation to delayed tamponade) are available. Second, given the low overall incidence of perforation, we chose not to have the angiographic core laboratory review all or a sample of cineangiograms in which a perforation was not noted. An underestimation of class I or II perforations might have resulted. Furthermore, the preprocedural correlates of perforation cannot be ascertained. Third, because patients were treated at the discretion of their interventionalist and not as part of any treatment evaluation protocol, we must be circumspect in making treatment recommendations (eg, we do not know if most class II perforations might have "sealed" without balloon inflation). Finally, these data probably reflect the early learning curve during the use of several of these devices, and the perforation incidences noted may be high. We were careful, therefore, not to conclude that the perforation rate with one of the ablative devices was necessarily greater than that of another.

Summary

Coronary perforation occurs more commonly with new coronary treatment devices that cut, abrade, or ablate as compared with balloon angioplasty and in women and the elderly, but the incidence of this complication with these new devices is low (1% to 2%). Perforations may be classified as to their risk of major complications such as tamponade, and such a classification scheme may help in the management of patients with perforation such that they receive optimal care.

Appendix

Contributing Centers and Investigators

Brigham and Women's Hospital (excimer laser, DCA), John Bittl, MD; Cedars Sinai Medical Center (excimer laser), Neal Eigler, MD, Frank Litvack, MD; Cleveland Clinic Foundation (PTCA, DCA, Rotablator, TEC), Stephen Ellis, MD, Patrick Whitlow, MD, Russell Raymond, DO, Anita Arnold, DO; Duke University (excimer laser, DCA, TEC); James Teheng, MD; Medical College of Virginia (PTCA, DCA, Rotablator, excimer laser), Michael Cowley, MD, Germano DiSciascio, MD, George Vetrovec, MD; Minneapolis Heart Institute (PTCA, excimer laser, DCA), Michael Mooney, MD; Mt Sinai Hospital (New York) (excimer laser), Timothy Sanborn, MD; University of California at San Diego (Rotablator), Maurice Buchbinder, MD; University of Michigan (PTCA, DCA, excimer laser), Stephen Ellis, MD, Eric Topol, MD; Washington Hospital Center (Rotablator, excimer laser, DCA, TEC), Kenneth Kent, MD, Martin Leon, MD, Jeffrey Popma, MD; William Beaumont Hospital (PTCA, TEC, DCA, Rotablator, excimer laser), Robert Safian, MD, William W. O'Neill, MD, Steven Ajluni, MD, Cindy Grines, MD.

Acknowledgments

The authors wish to express their gratitude to Patti Durnwald for her patience and expertise in the preparation of the manuscript.

References

1. Kimbiris D, Iskandrian AS, Goel I, Bemis CE, Gehl L, Owens J, Segal BL. Transluminal coronary angioplasty complicated by
Increased coronary perforation in the new device era. Incidence, classification, management, and outcome.
S G Ellis, S Ajluni, A Z Arnold, J J Popma, J A Bittl, N L Eigler, M J Cowley, R E Raymond, R D Safian and P L Whitlow

Circulation. 1994;90:2725-2730
doi: 10.1161/01.CIR.90.6.2725
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1994 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/90/6/2725

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org/subscriptions/