Laser Balloon Angioplasty: Clinical, Angiographic and Histologic Results

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Laser balloon angioplasty combines conventional coronary angioplasty with laser energy to transiently heat vascular tissue. Laser balloon angioplasty was performed in 21 patients (aged 56 ± 13 years), including 10 patients treated urgently after acute failure of conventional angioplasty and 11 patients treated with elective laser balloon angioplasty. Immediately after conventional angioplasty, laser doses (1 to 10 doses of 205 to 380 J each) were delivered during inflation of the laser balloon to a pressure of 4 atm.

Seven (70%) of 10 patients with acute failure of conventional angioplasty were successfully treated with laser balloon angioplasty, but 3 (30%) were unsuccessfully treated with the laser procedure and required emergency coronary artery bypass surgery. In all three failures, the 3 mm laser balloon angioplasty catheter was not the optimal size for the vessel. In the 11 patients treated with elective laser balloon angioplasty (reference diameter 2.94 ± 0.22 mm), the minimal luminal diameter increased from 0.45 ± 0.25 to 1.85 ± 0.46 mm after conventional angioplasty and to 2.44 ± 0.29 mm after laser balloon angioplasty (p < 0.001). This corresponded to a decrease in diameter stenosis from 84 ± 9% before to 35 ± 16% after conventional angioplasty and to 15 ± 10% after laser balloon angioplasty (p < 0.001). There were no instances of myocardial infarction, emergency coronary artery bypass surgery or death and no acute complications related to delivery of laser energy in this group.

Follow-up coronary angiography was performed 5.5 ± 1.1 months after laser balloon angioplasty in 18 patients discharged from the hospital after a successful procedure. Ten patients (56%) had angiographic restenosis, defined as recurrent diameter stenosis >50%. Six patients were subsequently treated by directional coronary atherectomy, which revealed intimal proliferation indistinguishable from that in patients with restenosis after conventional angioplasty.

In conclusion, laser balloon angioplasty may be effective in sealing severe coronary dissections and reversing abrupt closure associated with failed conventional angioplasty. After uncomplicated conventional angioplasty, laser balloon angioplasty improves immediate luminal dimensions, but restenosis appears to be mediated by intimal hyperplasia, similar to that seen after conventional angioplasty.

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Methods

Study patients. Between March 1, 1989 and October 1, 1990, 21 patients (aged 56 ± 13 years) undergoing their initial coronary angioplasty procedure were enrolled in a study of laser balloon angioplasty according to a protocol approved by the Committee on Clinical Investigations at Beth Israel Hospital (on November 21, 1988), as 1 of 12 centers investigating the use of this procedure. Ten patients underwent emergency laser balloon angioplasty as a salvage procedure after abrupt failure of conventional angioplasty and 11 patients underwent elective laser balloon angioplasty immediately after successful conventional angioplasty. The study group included 17 men and 4 women with anginal symptoms (Canadian Cardiovascular Society class I in 1 patient, class II in 4 patients, class III in 5 and class IV in 11), including 9 patients with postinfarction angina. Seventeen patients had single-vessel disease and four had multivessel disease.

Patient selection for emergency laser balloon angioplasty for failed conventional angioplasty. Patients in whom conventional angioplasty failed and who were considered acceptable candidates for coronary artery bypass surgery were eligible for inclusion. Conventional angioplasty failure was defined as: 1) abrupt closure (total occlusion with Thrombolysis in Myocardial Infarction trial [TIMI] grade 0 or 1 flow or severe dissection associated with impaired anterograde flow [TIMI grade 2 flow] and clinical signs of ischemia [ongoing angina associated with ST segment changes]); and 2) failure to reestablish effective anterograde flow (TIMI grade 3 flow) by prolonged (>3 min) inflations with a conventional or perfusion balloon catheter.

Patient selection for elective laser balloon angioplasty. All patients <76 years of age who were candidates for elective conventional angioplasty were considered for elective laser balloon angioplasty if they were acceptable candidates for coronary artery bypass surgery and if they were clinically stable (no angina within 12 h of angioplasty). Angiographic inclusion criteria included a single lesion in the target vessel with >70% diameter stenosis and <1 cm length. Patients with recent myocardial infarction (<5 days) before coronary angioplasty, total occlusion, bifurcation or ostial lesions or stenosis of a saphenous vein bypass graft were excluded. From March 1, 1989 to November 1, 1989, only lesions in a 3 mm vessel were considered because the 3 mm laser angioplasty balloon (LBA-II) was the only size then available. After November 1, 1989, 2.5, 3 and 3.5 mm balloons (LBA-III) became available for clinical investigation.

Conventional angioplasty procedure. All patients were treated with aspirin (325 mg/day) and dipyridamole (400 mg four times a day) ≥24 h before undergoing conventional angioplasty and this treatment was continued indefinitely after hospital discharge. After placement of the arterial sheath, heparin (10,000 U) was given intravenously and further doses were administered to maintain the activated clotting time between 250 and 300 s. Heparin infusion was continued for 12 to 24 h after angioplasty in elective cases. In patients treated successfully with emergency laser balloon angioplasty for failed conventional angioplasty, heparin infusion was continued until a therapeutic prothrombin time (15 to 16 s) was achieved with Coumadin (warfarin), which was given orally for 3 months after discharge.

All patients underwent right and left heart catheterization and conventional coronary angioplasty using a 0.014 in. (0.036 cm) guide wire (Advanced Cardiovascular Systems) advanced through an 8 or 9F guiding catheter (Schneider, USA). The lesion was dilated with appropriate size balloons using at least three inflations to 4 to 10 atm (60 to 150 psf) for 60 to 120 s per inflation. Additional balloon inflations were performed to achieve the best angiographic result and a minimal residual stenosis <50% (by visual estimate) if possible.

Laser balloon angioplasty catheter and laser delivery system. The laser balloon angioplasty system consists of a modified coronary angioplasty catheter and a laser source, as described previously (18). Briefly, the laser balloon angioplasty catheter (Spears laser balloon, USCI Division, C.R. Bard) is similar to a conventional angioplasty catheter with a 4.3F shaft and a polyethylene teraphthalate balloon measuring 20 mm in length. The original prototype for clinical use (LBA-II) was only available with a balloon measuring 3 mm in diameter and was used in the first 16 patients. The most recent design (LBA-III) is available with balloons measuring 2.5, 3 and 3.5 mm in diameter and was used in the last five patients. The triple-lumen catheter contains a central lumen to accommodate the guide wire, a second lumen for balloon inflation and a third lumen that contains the 100 μm silica fiber-optic, which terminates in a special diffusing tip. The diffusing tip of the LBA-III catheter provides more even distribution of laser energy over the length and circumference of the balloon compared with the LBA-II catheter. To enhance transmission efficiency of laser radiation, the balloon was inflated with a 50% solution of metrizamide (Amipaque, Sterling Drug) in deuterium oxide (D20, Merck and Co.), rather than water.

The laser source is a 20 W continuous wave neodymium:yttrium-aluminum-garnet (Nd:YAG) laser (Quantronix System 1500), which delivers laser radiation in the near infrared spectrum at 1,060 nm. Laser doses of 205 to 380 J each were delivered in a stepwise decremental dose format over 20 s (25 W for 5 s, 15 W for 5 s and 12 W for 10 s for the 3 mm LBA-II catheter); these doses have been shown to achieve tissue temperatures of 90° to 110°C in vitro (personal communication, W. Scott Andrus, USCI).

Laser balloon angioplasty technique. Patients were given fentanyl (50 to 100 μg) and midazolam (1 to 2 mg intravenously) immediately before laser balloon angioplasty for sedation and analgesia. The laser balloon catheter was positioned at the site of the original lesion and during inflation of the laser balloon to 4 atm, the guiding catheter was flushed with warmed (37°C) heparinized physiologic saline solution with potassium chloride (4 mEq/liter). After full balloon inflation was achieved, the same solution was
used to flush the central guide wire lumen to prevent binding of the guide wire to the balloon catheter during laser exposure. The programmed laser dose was delivered over 20 s, followed by continued balloon inflation for an additional 30 to 40 s, allowing the temperature of the arterial wall to return to normal. The balloon was then deflated and the laser balloon angioplasty catheter removed. Angiography was repeated to assess the final result and additional doses were delivered with the same laser catheter if clinically indicated. For elective cases, one to three laser doses (total dose 205 to 960 J) were administered, but in two emergency cases with long (>1 balloon length) dissections, multiple overlapping laser balloon inflations were performed, requiring 5 (total dose 1,600 J) and 10 (total dose 3,200 J) doses, respectively.

Lesion morphology. Lesions were classified as type A, B or C according to definitions of the American College of Cardiology/American Heart Association Task Force (19), based on lesion length, eccentricity and bend point >45°, as well as the presence of thrombus, ulceration and calcification. Anterograde flow was graded on a scale of 0 to 3 as defined by the TIMI study (20). The extent of arterial dissection was graded on a scale of 0 to 4 (0 = none; 1 = small intimal flap; 2 = moderate intimal flap and focal linear dye stain with normal anterograde flow; 3 = large dissection but with anterograde flow [TIMI grade 2 or 3 flow]; and 4 = abrupt closure without anterograde flow [TIMI grade 0 or 1 flow]).

Follow-up. Clinical follow-up was performed by telephone contact or clinic visit at 1-, 3- and 6-month intervals after hospital discharge. Graded exercise tests were performed at 3 and 6 months after laser balloon angioplasty. Coronary angiography was recommended for all patients at 6 months, but was performed earlier if clinically indicated for recurrent symptoms.

Quantitative assessment of angiographic results. Quantitative assessment of minimal lumen diameter and percent diameter stenosis was performed before and immediately after conventional angioplasty, immediately after laser balloon angioplasty and at the time of follow-up angiography, using the angiographic catheter as a reference diameter. Dimensions of magnified images were measured with electronic calipers (Digital Calipers System, Sandhill) as described previously (21,22). Views were matched for magnification, angle, skew and table height to obtain the optimal view of the lesion.

Histology. Six patients (five who underwent laser balloon angioplasty at Beth Israel Hospital and one who underwent the procedure elsewhere) with symptomatic restenosis after laser balloon angioplasty were treated by directional coronary atherectomy (Simpson AtheroCath, Devices for Vascular Intervention) at intervals of 76 to 247 days after laser balloon angioplasty. Tissue obtained at the time of atherectomy was fixed in formalin. Paraffin sections were stained with hematoxylin-eosin, Masson’s trichrome and elastic van Gieson and analyzed by conventional light microscopy.

### Table 1. Baseline Angiographic Characteristics of 21 Patients

<table>
<thead>
<tr>
<th>Lesion location</th>
<th>Failed PTCA (n = 10)</th>
<th>Elective LBA (n = 11)</th>
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<td>LAD</td>
<td>7</td>
<td>6</td>
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<tr>
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<td>1</td>
</tr>
<tr>
<td>RCA</td>
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<td>4</td>
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<tr>
<td>Lesion type*</td>
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<tr>
<td>A</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>B</td>
<td>6</td>
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<td>C</td>
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<tr>
<th>Lesion morphology</th>
<th>Failed PTCA (n = 10)</th>
<th>Elective LBA (n = 11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length (mean ± SD) (mm)</td>
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<td>3.8 ± 1.9</td>
</tr>
<tr>
<td>Eccentric</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
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<td>1</td>
</tr>
<tr>
<td>Thrombus</td>
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<td>4</td>
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<tr>
<td>Ulceration</td>
<td>0</td>
<td>4</td>
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*As defined in reference 19. LAD = left anterior descending artery; LBA = laser balloon angioplasty; LCx = left circumflex artery; PTCA = conventional coronary angioplasty; RCA = right coronary artery.

Statistical analysis. Values are reported as mean values ± SD. Angiographic variables were analyzed with analysis of variance (ANOVA) for repeated measures. Group comparisons were performed by using the unpaired Student’s t test for continuous variables and chi-square analysis for discrete variables.

### Results

Baseline lesion characteristics (Table 1). Lesions were located in any vessel and included the left anterior descending artery in 13 patients, the left circumflex artery in 2 and the right coronary artery in 6. Lesions were classified as a type A lesion in 8 patients and a type B lesion in 13; patients with a type C lesion were excluded. Although all lesions were discrete (length <10 mm), lesions were classified as type B because of lesion eccentricity in 13 patients, bend point between 45° and 90° in 3, angiographic evidence of thrombus in 6 and plaque ulceration in 4.

Emergency laser balloon angioplasty for failed conventional angioplasty. Ten patients underwent emergency laser balloon angioplasty because of abrupt failure of conventional angioplasty as a result of sudden closure (dissection grade 4 or TIMI grade 0 flow) in four patients and severe arterial dissection (dissection grade 3) with impaired anterograde flow (TIMI grade 2 flow) in six (Fig. 1). All four patients with abrupt closure had severe angina and ST segment elevation; in one of the four, it was associated with recurrent thrombus formation. All six patients with a severe dissection (grade 3) had angina with ST segment changes and delayed anterograde flow (TIMI grade 2).

The length of dissection could be estimated in nine patients and was <20 mm in five and >20 mm in four. Failed conventional angioplasty in the remaining patient was attrib-
The impact of emergency laser balloon angioplasty (LBA) on flow (TIMI grade) and severity of dissection (dissection grade) in 10 patients with acute failure of conventional angioplasty (PTCA) (see text for definitions). A, Laser balloon angioplasty resulted in normalization of anterograde flow in 9 of 10 patients. B, Three patients had persistent severe dissection (grade 3 or 4) requiring emergency coronary artery bypass surgery. Dissection grade could not be estimated in one patient with abrupt closure due to thrombus, who was managed successfully by laser balloon angioplasty. Each line represents one patient, unless otherwise indicated.

The mean luminal diameter after successful laser balloon angioplasty was 2.31 ± 0.47 mm, corresponding to a residual diameter stenosis of 19 ± 14%. Repeat angiography performed 12 to 24 h after angioplasty demonstrated continued arterial patency and normal anterograde flow in all seven patients (Fig. 2 and 3), with a mean luminal diameter of 2.14 ± 0.41 mm and a residual stenosis of 27 ± 10% (p = NS versus immediately after angioplasty). All patients were discharged from the hospital in stable condition 6.4 ± 2.2 days after the procedure once the prothrombin time was in the therapeutic range.
Failure of laser balloon angioplasty. This procedure was unsuccessful in three patients (30%), all of whom had persistent severe dissection (grade 3 dissection in two patients) or abrupt closure (grade 4 dissection in one patient) after laser balloon angioplasty despite the reestablishment of normal anterograde flow (TIMI grade 3 flow) in all three patients (TIMI grade 0 flow). Because of the unsatisfactory appearance of the dissections, all three patients were referred for emergency coronary artery bypass graft surgery after placement of an autoperfusion ("bailout") catheter despite the absence of ischemic symptoms or ST segment changes in two patients (Fig. 4).

Failure of laser balloon angioplasty was attributed to the lack of availability of appropriate size laser balloon angioplasty catheters or the presence of a long spiral dissection, or both. These failures included unsuccessful sealing of a 60 mm long dissection using a 3 mm laser balloon catheter in a 4 mm vessel in one patient (Fig. 4); unsuccessful sealing of a focal dissection with a 3 mm laser balloon catheter in a 2.5 mm vessel in one patient (angioplasty resulted in improvement in anterograde flow from TIMI grade 2 to 3 and resolution of symptoms and ST segment changes, but there was persistent grade 3 dissection in both of these patients); and successful sealing of part of a 60 mm long dissection using a 3 mm laser catheter in the mid-portion of a 3 mm vessel in one patient, which was not applied to the distal dissection, where the vessel measured only 2 to 2.5 mm in diameter.

Comparison of acute laser balloon angioplasty with conventional angioplasty. To place laser balloon angioplasty in perspective, all cases of abrupt failure of conventional angioplasty at Beth Israel Hospital in 1989 were reviewed. Among 689 conventional angioplasty procedures, 18 patients...
(2.6%) had persistent angioplasty failure despite conventional methods to reestablish effective anterograde flow. Of these 18 patients, 3 had abrupt closure of small sidebranches and were treated medically, 9 underwent attempted laser balloon angioplasty (the procedure was successful in 6 and unsuccessful in 3) and 6 underwent emergency coronary bypass surgery without attempted laser balloon angioplasty. Therefore, only 9 (1.3%) (3 with unsuccessful laser balloon angioplasty, 6 in whom laser balloon angioplasty was not attempted) of 689 patients required emergency surgery for failed conventional angioplasty. Laser balloon angioplasty was not attempted in six patients because of failure to successfully recross the occlusion in one patient and lack of an appropriately sized laser balloon catheter in five patients (a 3.5 mm vessel in three patients and a 2.5 mm vessel in two patients before the availability of the LBA-III catheter). Currently, all five of these patients, as well as the three in whom laser balloon angioplasty was attempted but failed (because of the lack of an appropriately sized catheter) would be better candidates for emergency laser balloon angioplasty.

Elective laser balloon angioplasty immediately after conventional angioplasty. In the 11 patients treated with elective laser balloon angioplasty, one to four laser doses were successfully delivered without catheter or system failures. The immediate angiographic results in three patients have been reported previously (16). Minimal luminal diameter increased from $0.45 \pm 0.25$ to $1.85 \pm 0.46$ mm after conventional angioplasty and to $2.44 \pm 0.29$ mm after laser balloon angioplasty. This decrease corresponded to a decrease in diameter stenosis from $84 \pm 9\%$ to $35 \pm 16\%$ after conventional angioplasty and to $15 \pm 10\%$ after laser balloon angioplasty ($p < 0.001$). Minimal luminal diameter after conventional angioplasty increased after laser balloon angioplasty in 10 of the 11 patients (Fig. 5). The only lesion that did not improve after laser balloon angioplasty was the lesion with the best result after conventional angioplasty (minimal luminal diameter 2.6 mm, 11% residual stenosis). A 3 mm laser balloon catheter was used after a conventional 3 mm balloon in 10 of the 11 patients; a 3.5 mm balloon was used in the remaining patient.

Conventional coronary angioplasty resulted in a residual
Complications. There were no deaths after laser balloon angioplasty. Acute myocardial infarction (peak creatine kinase $\geq$ 2 times the upper limit of normal) occurred in all three patients who required emergency bypass surgery (Q wave infarction in one, non-Q wave infarction in two) after unsuccessful emergency laser balloon angioplasty for abrupt failure of conventional angioplasty. One patient developed non-Q wave infarction after successful emergency laser balloon angioplasty, but this patient already had evidence of evolving infarction at the time the emergency procedure was initiated (abrupt closure occurred after sheath removal following conventional angioplasty, mandating that the total occlusion be recrossed and dilated).

The average time to laser balloon angioplasty from the onset of the last conventional balloon inflation was $31 \pm 14$ min (most of which was spent in transporting the laser to the appropriate room and warming up the laser). It is conceivable that this delay may have contributed to the extent of myocardial injury in patients with myocardial infarction, but it is likely that the contribution was small. In fact, myocardial infarction would have occurred in all 10 patients if laser balloon angioplasty had not been available.

Two patients required surgical repair of a femoral artery pseudoaneurysm (including one patient who also required a blood transfusion), which may have been related to the anticoagulation regimen prescribed after successful emergency laser balloon angioplasty.

Among the patients treated with elective laser balloon angioplasty, one patient with angiographic evidence of thrombus before conventional angioplasty subsequently developed progressive thrombus formation that lessened slightly after administration of intravenous dextran and intracoronary urokinase. This patient had successful laser balloon angioplasty (825 J) that was complicated by delayed thrombotic occlusion of the vessel (36 h later) and a small non-Q wave myocardial infarction (peak creatine kinase MB isoenzyme 17 U; normal <10 U). The occlusion was redilated by conventional angioplasty, which was followed by recurrent thrombus formation; subsequent repeat laser balloon angioplasty at a higher energy dose (960 J) resulted in successful recanalization. One patient developed a superficial groin infection at the site of sheath insertion, requiring antibiotics and local drainage.

During laser exposure, most patients experienced mild pain that generally lasted about 10 s and was distinct from their typical angina. Painful sensations did not require premature termination of laser delivery of radiation in any patient. After the laser procedure two patients had asymptomatic coronary spasm (distal to the tip of the balloon) that was managed successfully with intracoronary nitroglycerin.

Follow-up. Complete 6-month clinical and angiographic follow-up data were available for all 18 patients discharged from the hospital after successful laser balloon angioplasty, including 9 patients who presented with symptomatic restenosis between 4 and 6 months after the procedure and 5 asymptomatic patients who underwent mandatory follow-up.
angiography at 6 months. During the follow-up period, 10 (56%) of 18 patients developed angiographic evidence for restenosis (5 of 7 emergency and 5 of 11 elective laser balloon angioplasty procedures). The restenosis was managed by directional coronary atherectomy in five patients (Fig. 2), conventional angioplasty in four (Fig. 3) and medical therapy in one patient. The minimal luminal diameter at follow-up study in all patients was 1.31 ± 0.89 mm, corresponding to a diameter stenosis of 55 ± 29% (Fig. 5). From laser balloon angioplasty to the follow-up angiogram, the mean decrease in minimal luminal diameter was 1.07 ± 0.89 mm. Two patients had total occlusion of the treated segment at follow-up.

**Histology.** Six patients (five underwent laser balloon angioplasty at our institution and one had the procedure elsewhere) with restenosis after laser balloon angioplasty underwent coronary atherectomy 6.1 ± 0.8 months after an elective (n = 3) or emergency (n = 3) laser procedure. Light microscopy revealed atherosclerotic plaque in all patients, media in one patient and organized thrombus in three patients. Intimal hyperplasia was identified in all six patients and was virtually identical to that associated with restenosis after conventional angioplasty (Fig. 2).

**Discussion**

**Mechanisms of conventional and laser balloon angioplasty.** Conventional coronary angioplasty improves luminal dimensions by fracturing plaque and stretching the underlying vessel wall, which frequently leads to medial dissection and formation of intimal flaps (23). These changes are generally well tolerated, but in 6% to 7% of patients, dissection and associated thrombus may create local flow abnormalities that lead to acute vessel closure. In 50% of these patients, emergency coronary artery bypass graft surgery is required (1-4). Although most patients do not sustain acute closure, initial gains in luminal diameter may be limited by early elastic recoil and by the later development of intimal hyperplasia leading to restenosis. The ultimate goal of laser balloon angioplasty is to create a large smooth lumen in the hope of achieving better immediate and long-term results compared with those achieved with conventional angioplasty. Possible mechanisms of luminal improvement by laser balloon angioplasty include thermal welding of dissection flaps (15,24,25), elimination of elastic recoil and vaso­spasm (14,26), reduction in platelet activation, desiccation of thrombus and inhibition of smooth muscle cell proliferation.

Data from our study confirm that laser balloon angioplasty results in thermal welding of dissection flaps and less elastic recoil than that associated with conventional angioplasty. In patients with immediate failure of conventional angioplasty, the critical mechanism for successful laser balloon angioplasty was thermal sealing of dissection because conventional methods of repeat dilation were not successful in reestablishing adequate anterograde flow. The laser procedure failed to reverse abrupt closure when the size of the laser angioplasty balloon was improperly matched to the size of the vessel, suggesting that use of an undersized balloon might lead to insufficient pressure at the site of dissection and that an oversized balloon might lead to further mechanical disruption of tissue planes despite delivery of heat to the vessel wall.

The favorable impact of laser balloon angioplasty on elastic recoil is suggested by immediate improvement in luminal dimensions compared with that achieved with conventional angioplasty in 10 of 11 patients. Despite the use of a 3 mm balloon, conventional angioplasty resulted in a minimal luminal diameter of only 1.85 ± 0.46 mm (35 ± 16% stenosis) compared with 2.44 ± 0.29 mm (15 ± 10% stenosis) after laser balloon angioplasty. However, elastic recoil was not eliminated by laser balloon angioplasty because the minimal luminal diameter was still less than the diameter of the laser balloon.

Further studies are needed to determine the effects of laser balloon angioplasty on platelet activation, thrombus formation, vaso­spasm and smooth muscle cell proliferation. Anecdotal experience in the present study suggests that reversal of abrupt closure in one patient was associated with desiccation of thrombus (laser dose of 960 J). However, desiccation of thrombus is not certain because elective laser balloon angioplasty at a lower energy dose (825 J) in one patient with thrombus was complicated by delayed abrupt closure due to recurrent thrombus formation. The ideal laser dose required for desiccation of thrombus is not known. Furthermore, laser balloon angioplasty does not appear to completely inhibit smooth muscle cell proliferation because restenosis still occurs, apparently as a result of intimal hyperplasia identical to that associated with conventional angioplasty.

**Laser balloon angioplasty for abrupt closure.** Preliminary results from a multicenter trial (27) of laser balloon angioplasty in patients with acute closure after conventional angioplasty have shown a success rate of 95%. In the present study, the laser procedure was successful in 7 of 10 patients with failed conventional angioplasty due to severe dissection or abrupt closure, or both. The mechanisms of success included desiccation of thrombus in one patient, sealing of dissection in two patients and stabilization of dissection in four. Patients with failed conventional angioplasty in the present study would have required emergency coronary bypass surgery because maximal conventional methods (long inflations, perfusion balloons, dextran) were not successful in reestablishing adequate anterograde flow. The failure of laser balloon angioplasty to help three patients suggests that size of the laser balloon should be matched to the arterial diameter to achieve sufficient tissue pressure for thermal welding.

Preliminary studies (22,28) of intracoronary stents and directional coronary atherectomy devices suggest that these new techniques may prove useful for preventing or reversing abrupt closure. However, laser balloon angioplasty may be more easily and effectively applied to long (>20 mm) spiral
dissections, particularly in vessels of relatively small caliber (vessel diameter ~ 2.5 mm) and cases of abrupt closure due to thrombus, in which atherectomy devices and stents may be less effective.

**Laser balloon angioplasty after elective conventional angioplasty.** Preliminary results of a multicenter trial (17) of conventional angioplasty versus laser balloon angioplasty in 143 patients suggest that for single discrete (mostly type A) lesions in a 3 mm vessel, conventional angioplasty with a 3 mm balloon results in a residual lumen of 1.7 mm, whereas laser balloon angioplasty results in a further increase in luminal diameter to 2.3 mm. In our study, immediate application of laser balloon angioplasty after successful conventional angioplasty led to further improvement in minimal luminal diameter in 10 of 11 patients; in addition, luminal contour was improved by sealing dissection flaps in 6 of 8 patients. These data suggest that laser balloon angioplasty may improve the immediate angiographic result after conventional angioplasty by sealing dissections and reducing elastic recoil. However, the problem of elastic recoil has not been eliminated because a 3 mm laser angioplasty balloon results in a lumen measuring only 2.4 mm in diameter.

Laser balloon angioplasty may have a more important role in patients with a type B lesion, in which conventional angioplasty may be associated with a lower success rate (19). In fact, conventional angioplasty was unsuccessful (residual stenosis >50%) in three of seven patients with a type B lesion in this study, but all three patients had excellent angiographic results after laser balloon angioplasty.

**Laser balloon angioplasty and restenosis.** The incidence of restenosis after conventional angioplasty is highly variable and ranges from 20% to 70%, depending on the nature of the original lesion (7–12) and the definition of restenosis (29). When restenosis was defined as a residual stenosis >50%, follow-up angiography revealed a restenosis rate of 56%. Preliminary results of a multicenter randomized trial (17) of conventional versus laser balloon angioplasty (using laser doses reported in this study) suggest a restenosis rate of approximately 40% for both groups. The rates of restenosis may be >60% in patients treated with high dose laser balloon angioplasty (>435 J per dose) and those treated successfully by laser balloon angioplasty for failed conventional angioplasty (17, 27). Higher laser doses may achieve greater weld strength, but laser doses associated with very high tissue temperatures may lead to cicatrization. In patients with immediate failure of conventional angioplasty, the relative risk of emergency surgery (with a perioperative mortality rate of approximately 6%) must be weighed against the likelihood of restenosis and the associated risks of elective repeat angioplasty and coronary bypass surgery.

**Coronary histology after laser balloon angioplasty.** Results of coronary atherectomy in six patients indicated that restenosis is associated with intimal proliferation indistinguishable from that occurring after conventional angioplasty. Although laser balloon angioplasty led to improvement in immediate results compared with those of conventional angioplasty, it apparently did not inhibit the process of intimal cellular proliferation.

**Safety.** Although the number of patients in this study is small, the available data suggest that laser balloon angioplasty is safe. There were no major complications (Q wave myocardial infarction, emergency coronary bypass surgery or death) directly attributable to laser balloon angioplasty, and a successful procedure resulted in avoidance of emergency surgery in 7 of 10 patients. In patients treated with successful emergency laser balloon angioplasty, the incidence of myocardial infarction was 14%, which is identical to the incidence of myocardial infarction in patients with abrupt closure who undergo successful redilation by conventional methods (4). However, if a time delay is anticipated in readying the laser, a perfusion balloon or a reperfusion catheter should be used to avoid prolonged ischemia.

**Limitations.** There are several limitations of the present study. 1) Laser balloon angioplasty was performed with the original catheter prototype (LBA-II) in the first 16 patients, whereas the current catheter prototype (LBA-III) was used only in the last 5 patients. The diffusing tip of the LBA-III catheter has improved axial and radial diffusion of laser energy, but whether it results in a better clinical outcome is not known. 2) The optimal laser dose has not yet been determined and different doses may be required for different clinical indications (sealing of dissection, desiccation of thrombus, elimination of spasm and recoil). 3) Despite the apparent immediate improvement in luminal dimensions and contour after laser balloon angioplasty, the clinical significance of these observations is unknown. It seems reasonable that a larger immediate dimension should be associated with a larger dimension at follow-up study, but this speculation has yet to be substantiated. 4) The number of patients in this study is too small to permit conclusions about the incidence of restenosis. It is fair to conclude, however, that current laser balloon angioplasty technology will not eliminate the problem of restenosis, although future refinements in laser catheters and doses may be beneficial. 5) The relative merits of laser balloon angioplasty compared with conventional angioplasty and other new investigational devices must await the availability of future randomized trials.

**Conclusions.** Laser balloon angioplasty appears to have a promising role in the treatment of severe coronary dissections and reversal of abrupt closure associated with failed conventional coronary angioplasty by virtue of sealing dissections and desiccation of thrombus. Elective laser balloon angioplasty is more effective at enlarging acute luminal dimension than is conventional dilation with the same size balloon, particularly in complex lesions, by sealing dissections and reducing elastic recoil. Despite the acute improvements in luminal dimension and contour, however, laser balloon angioplasty does not prevent smooth muscle cell proliferation leading to restenosis. The relative merits of laser balloon angioplasty with respect to safety, as well as immediate and long-term efficacy, can only be established by a larger randomized trial.
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References