Results and Follow-up After Percutaneous Pulsed Laser–Assisted Balloon Angioplasty Guided by Spectroscopy

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Background. Few data are available on the long-term outcome of patients who undergo laser-assisted balloon angioplasty for recanalization of occluded peripheral arteries. Because the cost of laser angioplasty is high, the value of the method should be carefully analyzed before it can be considered a routine method for recanalization. The purpose of this study was to evaluate the early and late results of laser-assisted balloon angioplasty in patients who could not be recanalized by conventional techniques.

Methods and Results. Laser angioplasty was performed in 66 patients with total occlusion of the iliofemoral artery in whom mechanical techniques failed to recanalize the obstructed vessel. The system consisted of a pulsed dye laser operated at 480 nm, 2 μsec/pulse, 5 Hz, 50 mJ/pulse coupled into a 0.021-in. laser catheter. The treatment laser was connected with a diagnostic laser to induce tissue fluorescence for spectroscopic analysis via the same fiber. The treatment laser was emitted only when atheromatous tissue was recognized. After a pilot hole was created by laser emission, dilatation was performed to enlarge the channel. The mean length of occlusion was 8.8±6.1 cm. The primary success rate was 82%. It did not depend on the length of occlusion but was greater in non-calcified than in calcified lesions (88% versus 71%, p<0.03). Complications included seven early recurrences that could be recanalized and eight perforations without clinical sequelae. At a mean 18-month follow-up, 64% of the laser-treated arteries remained patent. The rate of patency was related neither to the length of the occlusion nor to calcifications but was lower in patients who had early reocclusion (p<0.02).

Conclusions. Pulsed dye laser-assisted balloon angioplasty is effective for recanalization of totally occluded arteries that cannot be treated by conventional means. The efficacy is limited by calcifications. The long-term patency rate is acceptable given the severity of the lesions. (Circulation 1991;83:787–796)

Laser-assisted balloon angioplasty is being extensively used for recanalization of occluded and stenosed peripheral and coronary arteries with various fibers such as thermal, \( \text{sapphire} \), \( \text{Nd-YAG} \), \( \text{argon} \), \( \text{excimer} \), and dye lasers. Because clinical applications of the technique have been only recently initiated, few data are available on the long-term outcome of patients who underwent these methods of recanalization (including pulsed dye laser angioplasty guided by laser-induced fluorescence). In addition, because the cost of laser angioplasty equipment and disposable laser catheters is high, a careful analysis of the value of the method is required before laser angioplasty can be considered a routine method for recanalization.

When applicable, the optimal means of evaluating laser angioplasty is to compare the results obtained by laser angioplasty with those obtained by conventional techniques in a randomized trial. However, the limited purpose of this study was to evaluate the early results of percutaneous pulsed laser–assisted balloon angioplasty in occluded peripheral arteries that could not be recanalized by conven-
tional techniques and to assess the late outcome of patients who underwent this method of treatment.

Methods

The laser angioplasty procedure used in this study has been described. Briefly, the system consists of a treatment pulsed dye laser operating at 480 nm with a pulse duration of 2 μsec and an energy of 35–50 mJ/pulse. The energy was transmitted through a laser catheter with a diameter of 0.021 in. consisting of a 200-μm optical silica fiber wrapped with a metal coil and marked with a radiopaque tip (Uniguide, MCM Laboratories, Mountain View, Calif.). The Uniguide was inserted into a special 5F balloon catheter with an internal lumen of 0.021 in. and a balloon diameter of 3–6 mm or a modified Van Andel catheter (Balt, Montmorency, France) consisting of an angulated tapered distal tip (3F), which allows the catheter to be rotated so that the optical fiber can be redirected toward the atheromatous target. Before each treatment laser emission, the tissue that was located against the distal tip of the optical fiber was analyzed with spectroscopy. The fluorescence was induced by a diagnostic helium–cadmium laser operating at 325 nm, a pulse duration of 50 μsec, and a power of 3 mW. The tissue fluorescence was transmitted back through the same fiber to be analyzed by a multichannel analyzer. A computerized logic system allowed the treatment laser to be emitted at the fiber tip if abnormal diagnostic spectra were recognized or the logic system inhibited the laser if nondiseased tissue was recognized. The number of diagnosis treatment cycles to be used at a rate of 5 Hz (between 10 and 100 Hz) was determined by the operators before each laser angioplasty sequence.

Patients

Between July 1, 1987, and October 30, 1989, 128 consecutive patients with totally occluded peripheral arteries were considered for laser-assisted balloon angioplasty in our institution. All patients had total occlusion of the iliac, superficial, or tibial artery and showed signs of ischemia. They all had undergone an attempt at recanalization with standard techniques. In 53 patients, the lesion could be mechanically crossed so that laser angioplasty was not indicated. In nine patients, the lesion could not be approached by either the guide wire or the balloon catheter. These patients were excluded from the study. In the remaining 66 patients, laser-assisted balloon angioplasty was performed only after failed attempts to successfully cross the occlusion with guide wires (Table 1).

Informed consent was obtained from each patient in accordance with a protocol approved by the ethics committee at the University Hospital Henri Mondor.

Before and immediately after the procedure, all patients underwent an arteriography and had their ankle–brachial index determined with the Doppler technique. Eleven patients had total occlusion of the iliac artery. Fifty-three patients had total occlusion of the superficial femoral artery, and two patients had total occlusion of the tibial artery (Figure 1). The mean length of occlusion was 5.8±4.5 cm (range, 1–17 cm) in iliac and 8.8±6.1 cm (range, 1–30 cm) in superficial femoral arteries. The mean length of calcified lesions was 11.0±7.0 and of noncalcified lesions was 7.2±5.4 cm (p<0.02). Lesions were classified as short (<5 cm), medium (5–10 cm), or long (>10 cm) occlusions. Calcifications were detected on the preoperative arteriograms and on fluoroscopy and cineangiography during the procedure. These were considered significant when clear-cut thick radiopaque outlines, located on the arterial wall at the site of the occlusion, were identified.

Follow-up consisted of clinical reevaluation that included symptoms, Doppler ankle–brachial index, and pulses every 3 months and repeated arteriography 2–6 months after the procedure. Fifty patients had clinical evaluation, but an arteriogram could only be obtained in 18 patients because the remaining 32 patients refused repeated angiography. Of the 18 patients who underwent repeated angiography, 14 were asymptomatic, two had reappearance of symptoms, and two were reevaluated for lesions that had been detected before the first procedure and that were considered for a subsequent recanalization procedure. There were no differences between the two groups of patients in clinical, angiographic, or technical characteristics. The distal runoff was assessed on angiograms by the number of patent arteries after the trifurcation.

Statistical Analysis

Mean±SD values were calculated for each variable. Postoperative patency rate was characterized by actuarial statistics with the Kaplan–Meier method.

<table>
<thead>
<tr>
<th>Table 1. Patient Characteristics</th>
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<tbody>
<tr>
<td>Age (yr)</td>
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<td>Range 35–86</td>
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<td>37</td>
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<td>&lt;3 patent calf arteries</td>
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<tr>
<td>29</td>
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<tr>
<td>Mean Doppler ankle–brachial index</td>
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<td>0.59±0.16</td>
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</tbody>
</table>
The $\chi^2$ and unpaired Student's $t$ test were used for comparisons between groups. A probability less than 0.05 was considered significant.

Procedure

The procedure has been described.\textsuperscript{15} Briefly, a percutaneous ipsilateral or contralateral approach (in three patients with iliac occlusion) from the femoral artery was performed with a 6F or an 8F hemaquet sheath with a side arm (USCI, Billerica, Mass.). After failed attempts at crossing the occlusion with a 0.020-in. guide wire (Schneider, Zurich) or a 0.035-in. guide wire (USCI), the Uniguide was inserted into the balloon catheter or the Van Andel catheter, and both were advanced against the occlusion with the distal tip of the fiber being positioned 5 mm beyond the catheter tip. After spectroscopic tissue analysis, the laser angioplasty procedure was initiated under fluoroscopic and angiographic control and continuous spectroscopic monitoring. As long as atheroma was recognized, the probe and treatment sequence was continued with gentle pressure maintained at the proximal end of the laser catheter to keep contact between the target tissue and the catheter tip. When normal tissue or blood was detected by spectroscopic analysis, the fiber was redirected with either balloon inflation or rotation of the angulated distal Van Andel catheter tip until atheroma could be recognized. After the occlusion was crossed, the catheter was advanced over the fiber. The fiber was pulled back and replaced by a 0.020- or a 0.025-in. exchange guide wire allowing subsequent dilatation. Additional balloon angioplasty was performed with 3–10-mm balloons at pressures of 4–8 atm for a duration of 1–3 minutes per inflation with a Baxter indeflator (Inflation-Pro, Santa Ana, Calif.). One day before and 6 months after the procedure, patients were given 250 mg aspirin/day. During the procedure, patients received 10,000 IU heparin.

Results

Primary Success

Recanalization of the occluded artery was obtained in 54 of 66 patients (82%) as assessed at control arterial angiography (Figure 2).

Laser angioplasty success was defined by the presence and free movement of the laser catheter tip downstream from the occlusion as determined by fluoroscopy and angiography. Success of primary laser-assisted balloon angioplasty was defined as resulting in a patent artery according to angiography after the procedure with a residual stenosis of less than 30%.

The actual size of the channel created by the laser could not be assessed by angiography because contrast injection was made through the sheath while the laser catheter was placed in the obstruction. However, on the basis of experimental data, the diameter of the channel created by pulsed lasers is generally thought to approximate the external diameter of the optical fiber.

The mean Doppler ankle–brachial index rose from $0.59\pm0.16$ before to $0.97\pm0.16$ after the procedure ($p<0.001$). The primary success rate was higher in iliac (91%) than in superficial femoral arteries (79%). Although the early success rate was greater in short (87%) than in long lesions (73%), it was not
Figure 2. Bar graphs of early success rates for laser-assisted balloon angioplasty. Panel A: Total early success rate was 82%, the early success rate for superficial femoral arteries (SFA) was 79%, and the early success rate for iliac arteries was 91%. Panel B: Success rate did not depend on the length of occlusion. Panel C: Success rate was significantly lower in calcified than in noncalcified occlusions (p<0.03).
significant. Noteworthy is the higher success rate in noncalcified than in calcified lesions (88% versus 71%; \( p < 0.03 \)). Moreover, comparisons of patients with short noncalcified lesions and those with long calcified lesions showed that the former had a 100% success rate, whereas the latter had only a 43% success rate. The causes of failure were the inability to penetrate the true lumen \((n=3)\), to cross calcified lesions \((n=7)\), or to advance the balloon catheter through the pilot channel \((n=2)\). The success rate was not significantly related to the number of patent calf arteries. The mean duration of the procedure for an average 8-cm-long occlusion was 90 minutes.

Complications

Complications included seven early reclosures that occurred within 24 hours after the procedure. They occurred similarly in short and long occlusions. In six patients, repeated dilatation was performed that was associated in three patients with thrombolysis, in one patient with thrombectomy, and in one patient with stent implantation. Only those patients received prolonged heparin therapy for 48 hours. There were eight perforations that were due in six patients to the mechanical effect of the sharp edge of the distal fiber tip. In two patients, perforation was associated with laser emission. Images of angiographic tears or subintimal track without any extravasation of contrast medium were observed in six patients. These complications were not associated with clinical sequelae, namely, major bleeding, and did not require any surgical treatment. There were neither spasms nor emboli. Amputation was required in three patients who were referred for limb salvage and whose arteries either could not be successfully recanalized (one patient) or had a poor runoff (two patients).

Follow-up

At a 1–33-month follow-up (mean, 18 months), the peripheral arteries of 32 of 50 (64%) patients were considered patent (Figure 3). Among the 54 primary successes, 50 patients were available for follow-up (one patient with acute reclosure had no repeated recanalization and three patients were lost to follow-up). Patency was defined either by digital subtraction or conventional arteriography in patients who underwent repeated arteriography. In the remaining patients who underwent clinical evaluation, patency was defined as the maintenance of the improvement in the Doppler ankle-brachial index and no more than 0.10 less than the postoperative index. The rate of patency was higher in iliac than in superficial femoral arteries (90% versus 55%). However, for statistical significance, it has to be taken into account that only a few iliac artery procedures were compared with a great number of superficial femoral artery procedures. Patients who had early reocclusion, albeit successfully recanalized, had a very low rate of long-term patency compared with those who had no early reocclusion (14% versus 67%). By contrast, the long-term patency was not influenced by the length of occlusion. Also, no relation was found between long-term patency and age, sex, severity of disease, or calcifications. The increase in the immediate postoperative Doppler ankle-brachial index was similar (+0.37) in long-term patent and occluded arteries. Thus, it has no predictive value for long-term patency. Twenty-one patent and six occluded arteries had a good runoff, whereas 10 patent and 11 occluded arteries had a bad runoff. Thus, no significant relation was found between the long-term patency and the distal runoff.

Discussion

Mechanical and Laser Recanalization

Our primary laser-assisted balloon angioplasty success rate (82%) was similar to that (83%) reported by Leon et al. This study shows that laser angioplasty may not be the only primary tool for recanalization of totally occluded arteries. In almost 50% of the cases, recanalization was obtained mechanically with conventional guide wires used to penetrate the obstruction. This fact was recently stressed by Ginsburg et al, who reported on recanalization of totally occluded common iliac arteries in 10 patients with a hydrophilic torsional guide wire. Therefore, before using a laser angioplasty device for creating a pilot hole, one should always attempt to recanalize occluded arteries with mechanical devices. On the other hand, this can result in subintimal tracks and consequently dissections. Indeed, the tendency of the guide wire is to be directed toward the site of least resistance and not necessarily to follow the path of the true lumen. By contrast, our spectroscopically guided laser angioplasty system, which is able to recognize atheromatous tissue, is likely to prevent penetration of the arterial wall and to redirect the laser catheter through the obstruction. In some of our cases, primary penetration of the guide wire into the arterial wall jeopardized the result of the procedure because it was subsequently impossible to guide the laser catheter through the true lumen. However, no comparison can be made between the perforation rate of laser angioplasty and that of conventional guide wire techniques because this study was not a randomized trial. Laser angioplasty was only used after failed mechanical recanalization. It may be hypothesized that if mechanical recanalization could have been used, the incidence of complications would have been high because of the progression of the catheter tip through long, hard, calcified total occlusions with an increased potential risk of perforation and dissection.

Indications for Laser Angioplasty

The fact that recanalization was more successful in iliac than in superficial femoral arteries suggests that interventional procedures should be preferentially considered in the former patients (Figure 4). In this way, patients who are poor candidates for a bypass
Figure 3. Graphs of long-term patency rates for laser-assisted balloon angioplasty. Panel A: Long-term patency rates were higher in iliac arteries (86%) than in superficial femoral arteries (55%). Panel B: Long-term patency was significantly lower in patients who had early reocclusion (14% vs. 67%). Panel C: Postoperative cumulative patency rate with life table analysis method.
operation can avoid major surgery by undergoing laser-assisted balloon angioplasty.

**Calcified Lesions**

One of the limitations of the technique is its inability to cross calcified lesions. It was previously thought that patients with highly calcified lesions were good candidates for pulsed laser angioplasty because in vitro experiments have shown that calcium can be penetrated with high-energy pulsed lasers\(^2\) but not by continuous wave lasers or guide wires. Moreover, these findings were partially confirmed by our clinical data that showed recanalization success in 14 of 21 calcified arteries (67%). Thus, calcified lesions still remain an adequate indication for pulsed laser angioplasty, but some restriction in the success rate has to be made. This limitation has been mentioned by Leon et al.,\(^1\) who pointed out that their two failures were related to heavy calcifications.

One of the interesting findings in our study was the relatively high primary success rate in long occlusions. This is in contradiction to previous studies on laser or conventional angioplasty that reported a low success rate in long lesions (>8 cm) especially when...
continuous wave lasers, thermal, or sapphire probes were used.\textsuperscript{6,10,11} Indeed, in our study, the success rate in patients with long occlusions was 73\% compared with 36\% in the patients reported by Sanborn et al.\textsuperscript{6} The greater effectiveness of pulsed dye laser angioplasty may be due to the high peak energy, the small diameter of the fiber that allows a high-energy density to be delivered into the obstruction, and the improved guidance of the laser catheter by fluorescence spectroscopy. Interestingly, the short-term success rate (82\%) in total occlusions reported by Grundfest et al.,\textsuperscript{27} who used an excimer laser, was identical to that in our study.

\textbf{Complications}

Early reocclusions could be successfully treated with conventional techniques. Thus, laser angioplasty did not prevent reocclusion from occurring, but it allowed access to lesions that otherwise could not have been treated by routine angioplasty. Laser angioplasty allowed routine angioplasty to be used as a secondary method of treatment. Although this observation favors the primary use of pulsed laser angioplasty combined with the secondary use of routine techniques, the prognosis of reopened early reocclusions is poor because arteries in only one of six treated patients remained patent at long-term follow-up.

The rates of perforation and dissection may appear high. High rates were also noted in a study by Leon et al.,\textsuperscript{18} in which 12 patients had two mechanical perforations. These were due mainly to manipulations of the laser catheter aimed at redirecting the distal fiber tip toward the obstruction target when signals of blood, thrombus, or healthy tissue were displayed by spectroscopic tissue analysis. Obviously, the distal tip should be smooth to prevent vessel wall damage. Also, two perforations were attributed to laser emission because the laser was active when perforation occurred. The perforations might have been due either to false recognition of target tissue within the vessel wall that caused the treatment laser to be activated and perforate the wall or to major involvement of the wall in atherosclerotic tissue so that atheroma was recognized and the treatment laser was subsequently activated. Because the site of perforation was not histologically examined, the cause of the complication could not be clearly elucidated.

\textbf{Spectroscopic Guidance}

The above-mentioned drawback of spectroscopic guidance may be further obviated by additional angioscopic\textsuperscript{28} or ultrasonic\textsuperscript{29} guidance that would be

\begin{figure}[h]
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\caption{Angiograms of occluded and recanalized artery. Panel A: Angiogram of a 4-cm totally occluded left superficial femoral artery. Panel B: Control angiogram of the recanalized artery 1 year after laser-assisted balloon angioplasty. Note that a short stenosis on the right superficial femoral artery appeared between the two angiograms.}
\end{figure}
able to determine the precise position of the laser catheter tip relative to the arterial wall and the obstruction. Indeed, laser-induced fluorescence tells us where not to go but not where to go. The usefulness of the spectroscopic feedback in reducing the rate of perforation requires further study. The issue should be addressed by comparing the rate of perforation occurring with the diagnostic system activated and the rate occurring without any spectroscopic feedback. However, the risk of perforation would probably be high when advancing the bare fiber through the obstructed artery only under spectroscopic guidance with neither mechanical fiber tip protection nor a complementary guiding system. The signals delivered by the spectroscopic diagnostic system were not consistently sufficient to easily redirect the laser catheter tip toward the obstructing target. When healthy tissue or blood was detected, the catheter had to be moved continuously until atheroma was recognized. This time-consuming manipulation was one of the major limitations of the system.

Follow-up

The follow-up may be subject to criticism. First, it was not available for all patients. Second, arterial angiography was available in only 18 patients (36%) (Figure 5). However, in all but three patients, clinical data and Doppler studies were available. Thus, even though assessment of either the frequency or the degree of restenosis was not possible in all cases, clinical and Doppler studies were sufficient to exclude a reocclusion or a significant restenosis. Indeed, patients who could not be assessed by repeated angiography were considered to have patent arteries only when they remained asymptomatic and the Doppler index was not significantly decreased compared with that obtained immediately after the procedure. Reports dealing with lower-extremity ischemia establish that patency can be assessed by a Doppler ankle–brachial index provided that it is not decreased by more than 0.10 compared with the postoperative index.22 The patency rate is acceptable given the severity of the lesions, and it is similar to that observed by others.5,7,11,14 We did not anticipate that the rate of long-term patency would be higher after laser-assisted balloon angioplasty than that observed after balloon angioplasty alone because in both series balloon dilatation was used that could have induced wall damage and initiated a similar process of restenosis or reocclusion. There is no reason why laser angioplasty would decrease the rate of reocclusion when combined with dilatation. This would be likely to occur only when laser had been used alone and when a great volume of tissue had been ablated. Clearly, very little tissue is removed by a single optical fiber, and much of the obstructive material is still present in the vessel after laser angioplasty. Thus, the main advantage of laser angioplasty appears to be the ability to penetrate total occlusions that cannot be penetrated by conventional means. Interestingly, the rate of patency was not significantly different in short and long occlusions. This finding is consistent with other studies.6,9,10 The only factor that played a role in long-term patency was early reocclusion. This was followed by secondary reocclusion even though primary conventional treatment had been successful.

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