Primary Success, Long-term Patency, Reporting Standards, and Indications for Peripheral Angioplasty Devices

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During the last 5 years, there has been a tremendous interest in the development of new devices for percutaneous treatment of peripheral and coronary artery obstructive arterial disease. As during the development of balloon angioplasty, many of these devices were first tested in peripheral arteries before their use in coronary arteries. Although this stage of new device development may no longer be necessary, it did serve to increase the interest in peripheral angioplasty as well as to generate some controversy about the appropriate indications for peripheral angioplasty. The key scientific issue is to determine the appropriate roles for these new devices relative to the existing treatment modalities of conventional balloon angioplasty and bypass surgery. Ideally, randomized trials would serve this purpose; however, these trials have yet to be organized for any new interventional device. In the interim, physicians have to rely on individual or multicenter reports with particular devices in order to determine their potential indications for use.

Standards for Peripheral Angioplasty Reports

Critical to the evaluation of new interventional devices is a set of common standards for reports dealing with peripheral arterial insufficiency, a need that is not new. In 1986, because of the lack of standardized reporting practices for peripheral revascularization, an ad hoc Committee of the Society of Vascular Surgery (SVS/ISCVS) recommended a set of definitions and classification criteria. These standards were proposed because of inconsistencies in the literature due to different definitions of immediate and long-term success or failure of revascularization procedures, incomplete descriptions of disease severity and risk factors that may affect outcome, and poorly defined terminology. A review of the peripheral angioplasty literature reveals similar inconsistencies and different definitions of a “successful” procedure.

In an attempt to clarify some of these issues our group recently used these SVS/ISCVS guidelines in reporting on the use of laser thermal angioplasty as an adjunct and in some cases an alternative to balloon angioplasty in peripheral arterial disease. At my suggestion, the report in this issue of Circulation by Pilger et al has also used the recommendations of the SVS/ISCVS in reporting on results with neodymium:yttrium aluminum garnet (Nd:YAG) laser sapphire tip angioplasty prior to conventional balloon angioplasty. Their report has also gone one step further by using intravenous digital subtraction angiography to assess patency at 6 and 12 months along with evaluation of symptom recurrence. Although echo-Doppler (Duplex) ultrasound imaging may be useful in assessing patency at specific sites after angioplasty, angiography as performed in the present study is superior for quick assessment of the anatomy in the lower extremities. One improvement on the SVS/ISCVS recommendations for the clinical assessment of peripheral revascularization would be a set of quantitative criteria for analysis of long-term patency, restenosis, and reocclusion, as has been suggested for the evaluation of coronary interventional devices. Certainly, if randomized or comparative trials of new devices are to be undertaken, angiographic analyses should be considered to be the method of choice for assessment of long-term efficacy. With this discussion as a background, what are the salient features of the study by Pilger et al?

Lasers as Recanalization Devices

One conclusion to be drawn is that the Nd:YAG laser contact probe is an effective recanalization device having a 79% success rate when conventional guidewires failed. By protocol design, an attempt was made to cross all occlusions with a soft guidewire before attempting laser recanalization. This approach resulted in a very low guidewire recanalization rate of 13%. As the authors discuss, this is a much lower success rate than before lasers were...
available. The use of the soft guidewire and a less aggressive attempt with the guidewire undoubtedly were key factors in this low guidewire recanalization rate. The problem with a more aggressive attempt with a guidewire is that the vessel may become dissected to the extent that it is no longer possible to safely attempt laser recanalization. By adding guidewire-recanalized cases (n=26) to the laser-treated cases, the overall recanalization rate for this series was 158 of 193 (82%), a recanalization or technical success rate higher than most reports for conventional balloon angioplasty, which average about 70%. In the initial report on the use of the argon heated metal probe in peripheral arterial occlusions, an overall 89% recanalization rate was observed. That series included successful laser thermal recanalization in eight of 11 (73%) occlusions in which “sustained” attempts with conventional guidewires had failed. In other multicenter reports on laser thermal assisted balloon angioplasty of peripheral arterial occlusions, recanalization rates have ranged from 80% to 85%. In our most recent series in which guidewire passage was attempted first, technical success was achieved in 81% of attempts; however, only 10 of 77 (13%) stenoses or occlusions could not be crossed first by a guidewire. Of these “impossible” lesions, 60% could be recanalized by the addition of the laser. These data suggest that laser catheters may be useful recanalization devices in that they can increase the recanalization success rate for peripheral arterial occlusions by about 10–15% (from approximately 70% to 80–85%) by recanalizing more than half of the occlusions that could not be crossed by a guidewire.

**Long-term Patency**

The real hope for most of the new angioplasty devices is that they will have an impact on improvement of long-term patency by diminishing restenosis or reocclusion more than balloon angioplasty does at present. Although laser or rotational (mechanical) energy may make it possible to recanalize a hard, fibrotic lesion that cannot be crossed with conventional guidewires, unless there is improvement in long-term patency there is no real net benefit in performing laser or mechanical recanalization followed by balloon angioplasty. In the study by Pilger et al, the cumulative patency rate of successfully opened vessels was found to be 63% at 36 months. By including those vessels that could not be successfully opened initially, the overall long-term success rate based on intention to treat is 79 of 167 or 47%. It is difficult to compare these results of combined laser assisted balloon angioplasty with those of conventional balloon angioplasty, laser or mechanical angioplasty, or bypass surgery because of possible differences in case selection, distal vessel runoff, or presence of risk factors that affect outcome. However, the 63% 3-year cumulative patency rate reported in this series may represent an improvement over previous reports with conventional balloon angioplasty. In particular, the 62% cumulative patency rate for lesions longer than 7 cm is very encouraging. The researchers also used particularly stringent angiographic criteria in reporting their follow-up data. This has not generally been the case in past reports of other peripheral recanalization procedures. One recent report of directional atherectomy for peripheral arterial stenoses and occlusions has also used angiography to analyze follow-up results. In that report there was a suggestion that directional atherectomy may have long-term results superior to conventional balloon angioplasty in eccentric stenoses. If we are ever to determine which interventional device yields the best long-term results for various anatomical situations, angiographic analysis will have to be included in such evaluations.

Another observation in the study by Pilger et al was the lack of difference in long-term patency between patients treated with aspirin and those treated with anticoagulation, as was also observed in a follow-up analysis of coronary angioplasty. The greater patency in older individuals seen in this study is intriguing; however, as the authors point out, this may be secondary to an increased number of smokers in a younger age group.

**FDA-Approved Role of Peripheral Laser Devices**

Is recanalization after guidewire failure the only role for a laser in peripheral angioplasty? Currently, it is the only FDA-approved indication; that is, it may be used when lesions are “difficult or impossible” to treat with conventional balloon angioplasty. For example, the package insert on the Laserprobe-PLR® device specifically states that “the device is not intended for use in cases where success or reestablishment of flow could reasonably be expected with the use of routine balloon angioplasty techniques.” Perhaps, if physicians adhered to these specific indications for use, there would not be as many letters to the editor written about the indiscriminate use or overutilization of laser angioplasty.

**Conclusions**

The study by Pilger et al demonstrates that an Nd:YAG laser sapphire tip catheter can recanalize a high percentage (79%) of peripheral arterial occlusions that could not be crossed with a less aggressive guidewire approach. Like previous metal cuffed laser devices, this sapphire tip catheter does appear to be able to recanalize occlusions that could not be crossed with a guidewire. The frequency with which this more expensive technology is required in routine peripheral angioplasty practice varies considerably, depending on how aggressively standard guidewire and supporting catheters are used. The encouraging long-term results found by Pilger et al, particularly in longer occlusions, warrant further investigation in well-conducted multicenter randomized clinical trials. To develop a rational approach for the use of new interventional techniques in the treatment of peripheral arterial disease, it seems imperative that clinical trials be developed with common standards.
and definitions as well as with the type of angiographic follow-up presented in this study.

References
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