Reporting standards for lower extremity arterial endovascular procedures

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Reports of endovascular procedures have proliferated in the surgery, radiology, and cardiology literature during the past decade. (A Medline search reveals more than 6000 articles written during the past 5 years alone.) However, the results of these reports are often difficult to interpret and compare, because investigators used differing methods of analyzing and presenting their data. For example, van Andel et al. reported a 90% success rate at 5 years for iliac balloon angioplasty based only on clinical criteria. In contrast, Johnston et al. reported a 61% success rate at 5 years when the criteria for success required both clinical and hemodynamic improvement. Blebea et al. recently showed a marked difference in patency rates when clinical and hemodynamic criteria were used separately and in combination. Moreover, Rutherford et al. pointed out that the 5-year patency rates of iliac balloon angioplasty can range from 52% to 89% at 5 years for the same group of patients depending on the different clinical and hemodynamic criteria used.

Several other factors can influence the results as well. The initial and long-term clinical success rates for transluminal percutaneous angioplasty depend on clinical indications (claudication vs limb salvage), lesion length, plaque composition (i.e., calcification), eccentricity of the lesion, lesion site, status of runoff vessels, and atherosclerotic risk factors. The patency rate can be improved by simply excluding from the analysis patients with initial technical failure.

Also, reporting patency rates of endovascular procedures with only a 6-month follow-up is inadequate and not predictive of long-term outcome, as noted in a recent atherectomy report. Suggested standards for reports dealing with lower extremity ischemia and its shortened version published previously by the JOURNAL OF VASCULAR SURGERY and the JOURNAL OF VASCULAR AND INTERVENTIONAL RADIOLOGY, respectively, address some of the requirements for endovascular reporting. However, these previous recommendations did not account for different lesion lengths, severities, or morphologic conditions; nor did they include some of the recently recognized complications specific to endovascular procedures (i.e., arterial rupture, distal emboli, dissections, and hemoglobinuria). Furthermore, these reporting standards assumed, but did not specify, that all patients undergoing the procedures must be included in the follow-up analysis.

Clearly, improved and uniform reporting standards for endovascular procedures are needed. The following are recommended guidelines for analyzing and reporting peripheral endovascular procedures. The existing standards for reporting lower extremity ischemia were modified to apply specifically to peripheral endovascular procedures.

PATIENT ASSESSMENT

Clinical evaluation. Stratification of patients by symptoms is mandatory, and the categories outlined previously by Rutherford et al. are recommended (Table I). The clinical grades I (claudication), II (rest pain), and III (tissue loss) account for the different natural history of each group. Grades I through III are subdivided further into categories 0 to 6 to allow objective comparison of postprocedural improvement or deterioration. The noninvasive laboratory description of a patient uses the absolute blood pressure rather than an ankle/brachial index (ABI) because the clinical status of the limb correlates much
Table I. Clinical criteria for categories of chronic limb ischemia

<table>
<thead>
<tr>
<th>Grade (Fontaine classification)</th>
<th>Category</th>
<th>Clinical description</th>
<th>Noninvasive laboratory description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>Asymptomatic, no hemodynamically significant occlusive disease</td>
<td>Normal results of treadmill/stress test*</td>
</tr>
<tr>
<td>I</td>
<td>1</td>
<td>Mild claudication</td>
<td>Treadmill exercise completed, postexercise AP greater than 50 mm Hg but more than 25 mm Hg less than normal</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Moderate claudication</td>
<td>Symptoms between those of categories 1 and 3</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Severe claudication</td>
<td>Treadmill exercise cannot be completed, postexercise AP less than 50 mm Hg</td>
</tr>
<tr>
<td>II</td>
<td>4</td>
<td>Ischemic rest pain</td>
<td>Resting AP of 40 mm Hg or less, flat or barely pulsatile ankle or metatarsal plethysmographic tracing, toe pressure less than 30 mm Hg</td>
</tr>
<tr>
<td>III</td>
<td>5</td>
<td>Minor tissue loss, nonhealing ulcer, focal gangrene with diffuse pedal ischemia</td>
<td>Resting AP of 60 mm Hg or less, ankle or metatarsal plethysmographic tracing flat or barely pulsatile, toe pressure less than 40 mm Hg</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Major tissue loss extending above transmetatarsal level, functional foot no longer salvageable</td>
<td>Same as for category 5</td>
</tr>
</tbody>
</table>

*Five minutes at 2 mph on 12-degree incline.

Table II. Adjunctive hemodynamic criteria for categorizing chronic limb ischemia

<table>
<thead>
<tr>
<th>Pulse volume recordings</th>
<th>Doppler wave recordings:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = Absent</td>
<td>0 = Absent</td>
</tr>
<tr>
<td>1 = Abnormal</td>
<td>1 = Abnormal</td>
</tr>
<tr>
<td>2 = Blunted</td>
<td>2 = Abnormal</td>
</tr>
<tr>
<td>3 = Normal</td>
<td>3 = Normal</td>
</tr>
<tr>
<td>No pulsatile perfusion</td>
<td>No Doppler sound</td>
</tr>
<tr>
<td>Markedly (30% to 99%) reduced amplitude, slow rise/fall</td>
<td>Monophasic wave</td>
</tr>
<tr>
<td>Slightly (10% to 29%) reduced amplitude, no dicrotic notch</td>
<td>Biphasic wave</td>
</tr>
<tr>
<td>Good pulse amplitude, dicrotic notch present, rapid rise</td>
<td>Triphasic wave</td>
</tr>
</tbody>
</table>

better with the absolute blood pressure. For example, a patient can move up or down a clinical category by a change in the cardiac output but without a change in the ABI, because the cardiac output affects the arm and ankle pressures equally.

**Hemodynamic assessment.** To allow comparison of groups of patients, as well as the therapeutic results of an individual patient, objective hemodynamic test results must be provided. Doppler pressure measurements in the form of resting ABIs are a minimum requirement. An exercise ABI is recommended when applicable. In cases of noncompressible arteries, particularly in diabetic patients, other objective measurements must be provided. Alternative objective noninvasive tests include pulse-volume recordings and Doppler waveforms. Table II lists the objective criteria recommended in reporting these alternative noninvasive hemodynamic tests.

**Risk factors.** Patients should be classified according to whether they have a history of smoking, hypertension, diabetes mellitus, or hyperlipidemia (increased total cholesterol or triglyceride levels or decreased high-density lipoprotein cholesterol levels), because these factors may influence long-term outcome. Other manifestations of coronary, cerebral, renal, and pulmonary disease should be reported because these factors may influence perioperative morbidity and mortality rates. The detailed grading system reported previously by Rutherford et al. can be used for categorizing these risk factors.

**DESCRIPTION OF LESION**

**Location.** Short- and long-term results are clearly related to the location of the treated lesion.* Thus the lesion should be classified by its anatomic site(s) (i.e., aorta and common iliac, external iliac, common femoral, deep femoral, superficial femoral, popliteal, anterior tibial, tibioperoneal trunk, posterior tibial, peroneal, and pedal arteries).

**Type.** Several investigators recently have shown that early and late results may be influenced by the type or characteristics of the lesion. Thus lesions should be categorized according to occlusion versus stenosis, diffuse versus focal, eccentric versus concentric, polyploid versus ulcerated versus smooth,
and calcified versus noncalcified. This information should be documented and obtained by angiography, endovascular ultrasonography, or duplex scanning. The most severe lesion should be considered in grading diffusely diseased arteries.

**Length.** Several investigators have clearly shown that early and late results are strongly influenced by the lesion length of the lesion. The length of the treated lesion should be separated into the following categories: ≤ 2 cm, > 2 cm to 5 cm, > 5 cm to 10 cm, and > 10 cm. If the sample size is too small to allow for categorization of the lesions into the four separate categories, the length to the nearest centimeter for each patient and the average lesion length for the group should be reported.

**Runoff vessels.** Although the status of runoff vessels has little influence on autogenous bypass results, its influence on endovascular procedures has been shown recently by several authors. Thus the status of the runoff vessels should be provided and graded as either poor (0 to 1) or good (2 to 3). Runoff is defined as an adequately patent (< 50% angiographic stenosis) artery distal to the treated site. The superficial and deep femoral arteries are the runoff vessels for iliac artery procedures, and the tibial arteries are the runoff vessels for femoral or popliteal procedures. Alternatively, the more detailed Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) runoff grading system can be used.

**Combined grading of lesion.** One may elect to combine the various categories listed above. Table III outlines a proposed grading scheme that represents an arbitrary attempt to set up a simple classification to allow comparison of different studies. As more becomes known, this classification may need modification in the future. Type A represents the most favorable lesions and includes discrete, focal, noncalcified, stenotic lesions less than 2 cm in length with two to three runoff vessels. Type C lesions are the least favorable and include diffusely diseased or occlusive lesions greater than 10 cm with unfavorable morphology and no to one runoff vessels. Type B includes lesions 3 to 10 cm in length. Type B is subdivided further into type B1 and B2 depending on the predominance of the other factors.

**Lesion modification.** When the lesion is modified by adjunctive therapy (i.e., thrombolysis), the premodification and postmodification lesions should be described and categorized separately.

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**Table III. Grading of disease severity for peripheral endovascular procedures**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Type A</td>
<td>Focal stenosis ≤ 2 cm length, concentric, smooth, noncalcified lesion, 2 to 3 runoff vessels</td>
</tr>
<tr>
<td>Type B1</td>
<td>Lesion length 3 to 10 cm, majority of other features more characteristic of Type A</td>
</tr>
<tr>
<td>Type B2</td>
<td>Lesion length 3 to 10 cm, majority of other features more characteristic of Type C</td>
</tr>
<tr>
<td>Type C</td>
<td>Diffuse disease or occlusion &gt;10 cm length, eccentric, ulcerated, or polyploid, heavily calcified lesion, 0 to 1 runoff vessels</td>
</tr>
</tbody>
</table>

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**CRITERIA FOR EARLY SUCCESS**

Treatment outcome should be based on the intent to treat and must include all patients who consent to undergo the procedure and go to the endovascular room. When more than one procedure is performed on the same arterial segment by combined endovascular therapy (i.e., thrombolysis plus percutaneous transluminal angioplasty [PTA], laser plus PTA, laser plus atherectomy), each must be evaluated and reported separately, indicating what each procedure achieved. However, both procedures must be successful to count as a procedural clinical success for the patient. For example, if laser effectively opens a pilot hole but PTA is unsuccessful, the entire procedure is considered a clinical failure for the patient.

In situations in which the endovascular procedure is performed in conjunction with a surgical reconstruction or another endovascular procedure of an adjacent inflow or outflow vascular bed, the patency rates of each vascular bed should be reported separately. However, a clinical or hemodynamic failure for the patient should be considered a failure for each of the procedures. For example, if an iliac angioplasty site remains patent but a femoropopliteal graft thromboses (or vice versa), leading to recurrent symptoms and a significant drop of the ABI, both procedures are considered to have failed.

Thus the therapeutic results must be based on clinical, hemodynamic, and imaging (i.e., angiography, magnetic resonance imaging, and ultrasonography) factors. All three criteria factors must show improvement to count as a successful result for the patient. The definition of improvement or success for each factor must be outlined clearly in the report, and the following definitions are recommended.

**Clinical success.** Clinical success must include symptomatic improvement, such as resolution or improvement of claudication (≥ 50% improvement), for patients with this symptom or resolution of rest pain and foot salvage for patients with...
limb-threatening ischemia. The patient must improve at least one category level listed in Table I.

**Hemodynamic improvement.** Hemodynamic improvement is defined as an improvement of the ABI of more than 0.15 as a stand-alone criterion (because ± 0.15 is reproducible) or 0.10 if associated with categoric clinical improvement (because ± 0.10 may be within laboratory error). For example, if a patient with an ankle pressure of 30 and arm pressure of 150 (ABI = 0.20) undergoes successful iliac balloon angioplasty clinically (resolution of rest pain) and radiographically but an occluded untreated superficial femoral artery/popliteal segment allows the ankle pressures to rise from 30 to only 51, the procedure should be considered a success even though the ABI increased from 0.20 to only 0.34. For another example, if a patient with a resting ankle pressure of 129 and arm pressure of 150 (ABI = 0.86) undergoes superficial femoral artery balloon angioplasty to give an ABI of 150/150, the rise of the ABI by 0.14 should be considered a hemodynamic success only if the patient demonstrates a categoric (Table I) clinical improvement.

For an iliac lesion treated in the presence of an untreated occluded superficial femoral artery, a thigh/brachial index may be used instead. In the presence of noncompressible vessels, the ABI should not be used, and pulse-volume recordings or Doppler waveform recordings should be provided instead. The patient should improve at least one hemodynamic category level listed in Table II.

**Anatomic success.** Anatomic success should be defined as residual luminal stenosis of less than 30% of normal diameter by angiographic biplane views or other similar accepted imaging techniques (i.e., ultrasonography, duplex imaging, and magnetic resonance imaging or angiography). The successful passage of the device through the lesion without angiographic or ultrasound evidence of adequate restoration of lumen size should not be reported separately as a technical success.

**CRITERIA FOR CONTINUED SUCCESS**

The above criteria for early success apply to immediate postprocedure, in-hospital results. Continued success is determined once the patient is discharged and is defined as maintenance of the same criteria listed above for clinical, hemodynamic, and anatomic success. Clinical patency must be based on sustained improvement of at least one objective hemodynamic or imaging test in addition to the clinical evaluation. A deterioration of one or more category level clinically (Table I) or hemodynamically (Table I and II) constitutes failure. Anatomic failure is defined as restenosis to 50% or greater of normal diameter by angiographic or other similar imaging assessment.

Primary and secondary patency rates should be reported as previously recommended by the SVS/TSCVS reporting standards.13 Because some patients require multiple serial interventions (i.e., repeat PTA in 4 to 6 months), it may be helpful to report assisted primary patency rates. However, the treated artery must have uninterrupted sustained patency, and the actual primary and secondary patency rates must also be reported. Cumulative patency rates should be calculated according to life-table analysis and must include all patients on whom the procedure was attempted and not just successfully treated patients. Valid life-table data (i.e., standard error <10%) to a minimum of a 2-year follow-up are required to determine long-term patency rates. Valid data to only a 6-month follow-up are considered short term, and data to 6 to 24 months are considered intermediate.

**COMPLICATIONS**

Complications should be categorized as procedure versus nonprocedure related. Procedure-related complications include local infections, arterial wall injury, dissections, thromboemboli, fistulas, hematomas, acute occlusions, perforations, vasospasm, contrast-induced or contrast-exacerbated renal failure, and hemoglobinuria/hemoglobinemia. Non-procedure-related complications may include aterectasia, congestive heart failure, arrhythmias, deep venous thrombosis, pulmonary embolism, and hypercoagulable states. However, any complication that occurs within 24 hours of the procedure should be considered procedure related. Deaths occurring within 30 days or during the same hospitalization should be counted as procedure related.

**PERIOPERATIVE FACTORS**

The report should provide clear technical details of the endovascular procedure. For balloon angioplasty, the report should note the balloon size and pressures and the duration of balloon dilatation. For ablation procedures, the report should note the type and size(s) of dilatation catheter(s) used, the rotational speed for the dilatation device, and the duration of the dilatation device application. For laser angioplasty, the report should note the laser wavelength, power settings, energy flux, duration of laser treatment, the method of laser energy delivery, and whether the laser was used as a stand-alone
procedure or an adjunct to balloon angioplasty or atherectomy.

Perioperative pharmacologic therapy should be outlined in detail. The use of aspirin, heparin, Coumadin, vasodilators, and thrombolytic agents should be listed, as well as duration and dosage of administration.

CONCLUSION

Presented herein is a modified version of the previously published reporting standards for lower extremity ischemia. Major modifications have been made to accommodate new concepts and issues that are pertinent or unique to endovascular procedures. Because endovascular procedures are evolving rapidly, the need to update the reporting standards periodically is anticipated. The guidelines presented above represent the minimum requirements to allow proper interpretation and comparison of different reports and devices. Adherence to these guidelines is recommended for future publications.

REFERENCES


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