Recommended standards for reports dealing with lower extremity ischemia: Revised version

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Recommended standards for analyzing and reporting on lower extremity ischemia were first published by the *Journal of Vascular Surgery* in 1986[1] after approval by the Joint Council of The Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery. Many of these standards have been accepted and are used in the current literature on peripheral arterial occlusive disease. With the passage of time, some oversights, aspects that require clarification, and better modifications have been recognized. This report attempts to correct these shortcomings while reinforcing those recommendations that have proven satisfactory. Explanatory comments are added to facilitate understanding and application. This version is intended to *replace* the original version. (J Vasc Surg 1997;26:517-38.)

DEFINITIONS AND CLASSIFICATION CRITERIA

The progression of disease in a chronically ischemic extremity may occur in a stepwise fashion, with each step representing an acute occlusive event. Therefore, reports that deal with the management of lower extremity ischemia should *not* mix these, or other acute ischemic episodes, with chronic ischemic states, because the results of emergency and elective interventions for the two are influenced by different variables and are not comparable. Furthermore, *different classification criteria should be used for acute and chronic ischemia when attempting to stratify limbs according to severity of ischemia.*

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Acute ischemia

The following categories for stratifying levels of severity of acute limb ischemia are recommended (Table I).

I. "Viable": *not immediately threatened*; no continuing ischemic pain, no neurologic deficit, skin capillary circulation adequate; clearly audible Doppler arterial flow signals in a pedal artery.

II. "Threatened" viability: *implies reversible ischemia in a limb that is salvageable without major amputation if arterial obstruction is relieved quickly.* Two levels within this category are recognized for therapeutic purposes, and their differences are tabulated in Table I: IIa—*marginally threatened* and IIb—*immediately threatened.* Neither category has clearly audible Doppler signals in pedal arteries. Patients who have *marginally* threatened extremities (IIa) may experience numbness and have transient or minimal sensory loss, limited to the toes. Continuous pain is absent. In contrast, *immediately*

Table I. Clinical categories of acute limb ischemia

		Findings		*Doppler signals*	
Category	*Description/prognosis*	*Sensory loss*	*Muscle weakness*	*Arterial*	*Venous*
I. Viable	Not immediately threatened	None	None	Audible	Audible
II. Threatened					
a. Marginally	Salvageable if promptly treated	Minimal (toes) or none	None	Inaudible	Audible
b. Immediately	Salvageable with immediate revascularization	More than toes, associated with rest pain	Mild, moderate	Inaudible	Audible
III. Irreversible	Major tissue loss or permanent nerve damage inevitables	Profound, anesthetic	Profound, paralysis (rigor)	Inaudible	Inaudible

threatened (IIb) limbs have persistent ischemic rest pain, detectable loss of sensation above the toes or a *continuing* lack of *all* sensation in the toes, and/or *any* motor loss (paresis or paralysis).

III. Major, "irreversible" ischemic change: predictably *will require major amputation or suffer significant, permanent neuromuscular damage regardless of therapy.* Profound sensory loss and muscle paralysis extending above the foot, absent capillary skin flow distally, or evidence of more advanced ischemia (e.g., muscle rigor or skin marbling) are present. Neither arterial nor venous flow signals are audible over pedal vessels.

COMMENT: Temporal criteria (e.g., 6 to 12 hours of ischemia) are not included in these reporting standards because the event of tissue damage also depends on location of occlusion, existing collateral circulation, and other factors. More definitive tests of tissue viability are still needed. At this time, "reversibility" of ischemia or "salvageability" of the foot or limb cannot always be accurately predicted even by those with considerable clinical experience. The original grouping of patients into "viable," "threatened," and "irreversible" categories was thought to be of value not only in comparing the results of treatment but in determining appropriate therapy. Its intent was to separate patients into those, at one extreme, who were clearly viable, in whom there was time for deliberate, detailed evaluation, and in whom intervention *might* not even be ultimately required, and those, at the other extreme, who would inevitably suffer major tissue loss (amputation) or permanent ischemic nerve or muscle damage, such that the goal of a painless, functional limb could not be achieved regardless of the rapidity and extent of revascularization. This left an intermediate (threatened) group of patients who required prompt revascularization to achieve limb salvage and usually needed to be taken directly to the operating room without preliminary angiography and with a minimum of diagnostic studies. Were it not for advances in thrombolytic therapy, and some misinterpretation of the original scheme, these three basic categories might still suffice, even if not infallibly predictive of outcome. The original criteria for a *viable* limb included *"ankle pressure above 30 mm Hg"* in addition to audible Doppler flow signals in pedal arteries, as originally suggested by Lavenson et al.[2] Unfortunately, some investigators focused more on this level of ankle pressure (30 mm Hg) than on audible arterial flow signals and other more important criteria in separating categories I and II.[3] A four-level modification of the original SVS/ISCVS scheme was ultimately proposed for stratifying patients with thrombosed native arteries and arterial grafts, using a 30 mm Hg ankle pressure to separate the first two levels of acute ischemia.[3] The reported results with more severe levels of ischemia using this scheme clearly did not fit with the intent or reality of the SVS/ISCVS scheme, claiming success with lytic therapy in the *majority* of those classified as "irreversible"! It seems apparent from this and other reports of the results of thrombolytic therapy that many cases were included that were not truly "acute" in the usual surgical sense. Furthermore, the concept of what can be considered *acute* limb ischemia has clearly been stretched in recent prospective randomized trials of thrombolytic therapy compared with surgery. For example, in the STILE trial the vast majority of cases were more than 14 days after arterial thrombosis.[4] Nevertheless, it has become evident that there is a subgroup of patients whose limb viability was originally defined as being "threatened" (typically those who had no audible Doppler pedal artery signals but only mild or evanescent sensory loss) in whom limb salvage could be achieved with a

Table II. Clinical categories of chronic limb ischemia*

Grade	*Category*	*Clinical description*	*Objective criteria*
0	0	Asymptomatic—no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise†; AP after exercise >50 mm Hg but at least 20 mm Hg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise† *and* AP after exercise <50 mm Hg
II*	4	Ischemic rest pain	Resting AP <40 mm Hg, flat or barely pulsatile ankle or metatarsal PVR; TP <30 mm Hg
III*	5	Minor tissue loss—nonhealing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP <60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP <40 mm Hg
	6	Major tissue loss—extending above TM level, functional foot no longer salvageable	Same as category 5

AP, Ankle pressure; *PVR,* pulse volume recording; *TP,* toe pressure; *TM,* transmetatarsal.
*Grades II and III, categories 4, 5, and 6, are embraced by the term chronic *critical* ischemia.
†Five minutes at 2 mph on a 12% incline.

more time-consuming approach, for example, catheter-directed thrombolytic therapy. This created a weakness in our original scheme, especially now that improved catheter-directed techniques and high-dose protocols can achieve improved perfusion in one third to one half of the time formerly required for lytic therapy. Therefore, we have subdivided category II into two levels, with the implication that there is time in level 2a patients for angiography or some other needed studies before embarking on the most appropriate revascularization procedure, *as long as close surveillance is maintained.* In level 2b, immediate revascularization is required. This change should help clarify reports of treatment outcome in this intermediate level of acute limb ischemia.

Finally, it is recommended that cases of arterial thrombosis and embolism *not* be mixed together or, if they are combined, the distribution of cases into these categories should be clearly stated. Cases of atherothrombotic microembolism ("blue toe syndrome") usually have transient focal ischemia, occasionally with minor tissue loss, but without diffuse forefoot ischemia. Therefore, they should either be not included in reported experiences of acute arterial thromboembolism or placed in category I (viable). As discussed further below, the practice of including such cases of transient focal ischemia in with cases of chronic critical ischemia is also inappropriate.

Chronic ischemia

A suggested classification for grading the severity of chronic arterial occlusive disease for the purposes of standardized reporting practices is outlined in Table II. Symptomatic disease is stratified into six categories to provide the greater breadth required for many clinical research reports. Thus categorical clinical improvement (discussed later) is made possible *within* the broad heading of claudication by subdividing it into three levels, and gangrene is divided into two levels according to its extent and the possibility of salvaging a functional foot remnant. Simpler broader gradations, based on Fontaine's original clinical staging, are offered in parallel. In both, a zero category or grade has been used to identify those who have no symptoms, or merely sensations of coldness *and* either no clinical signs of occlusive disease or modest pulse diminution. Such a category or grade is valuable because it also allows postoperative improvement to be gauged at all levels. It is also in keeping with the practice of assigning "zero" to asymptomatic stages of disease in SVS/ISCVS reporting standards. However, this results in different numbers being assigned to the Fontaine-equivalent grades than has been common practice in Europe. Also, although it has become common practice in Europe to divide patients with claudication (grade I) into two levels (Fontaine stages IIa and IIb) to indicate disability, such an imprecise separation is not recommended here.

Before discussing the criteria for classification of chronic ischemia, a number of terms require definition and clarification.

Claudication means extremity pain, discomfort, or weakness that is consistently produced by the same amount of walking or equivalent muscular activity in a given patient and that is promptly relieved by cessation of that activity. Ordinarily, claudication implies ischemic muscle pain induced by exercise,

and as such may be identified as hip, buttock, thigh, or calf claudication. The severity of claudication can be reliably related to time and distance walked only if speed and incline grade are also standardized. The speed, incline, and time recommended here are fairly standard for routine studies in North American vascular diagnostic laboratories. However, for clinical trials such a constant load protocol may not be as appropriate as a graded load protocol in which the incline is increased at timed intervals.[4] The latter protocol appears to have better reproducibility and minimal placebo effect. Only when standardized protocols are used can the effects of treatment be accurately assessed and different therapies compared.[5]

Qualifying candidates for therapeutic intervention as "disabled" patients with claudication or with "less than one block" claudication is convenient, and adequate for some clinical practices, but not precise enough for categorizing patients in clinical research studies or trials. Disability is relative, being related to activity levels governed by age, occupation, and avocational interests. Disability is better gauged by a more comprehensive analysis of activities and capabilities, such as community-related activity or walking impairment questionnaires or other similar quality of life instruments.[6] Therefore, "disabling" claudication, although an acceptable indication for intervention in carefully selected patients, is no more acceptable as a categorizing criterion than "less than *x* blocks claudication distance." Either the broad grade of intermittent claudication (grade I or Fontaine grade II) should be used, or objective and reproducible criteria for further stratification must be used, for example, using the *categorical* criteria recommended in Table II. However, stratifying patients by walking distances using a standardized treadmill protocol is appropriate for therapeutic clinical trials, and here either *initial claudication distance* (ICD; distance before onset of pain) or *absolute walking distance* (ACD; distance at which patient is forced to stop because of pain) should be specified. Thus patients with claudication need further separation only for the comparative purposes of clinical investigation.

Resting ankle systolic pressure measurements alone will not cleanly separate patients with claudication according to degree of symptom severity, although it has been shown that those in the lower range of resting ankle-brachial index (ABI) or ankle pressure clearly have a worse prognosis.[7-12] The noninvasive vascular laboratory test criteria recommended in Table II were chosen to represent first the minimum acceptable objective evidence of claudication, designated as "mild." Then the categories of "moderate" and "severe" were further defined by whether the patient could complete 5 minutes on the treadmill at a standard speed and incline. A reduction in ankle pressure after this exercise to 50 mm Hg or less was also required in the latter two categories to confirm that ischemia was responsible for the limiting pain. Claudication may be experienced without the ankle pressure being reduced to this level, but it is usually "mild." Thus if the duration of ambulation is less than 5 minutes or if the patient can only ambulate for 5 minutes by reducing treadmill speed or incline, the patient qualifies as having *severe* claudication. In testing patients with claudication, Wilbur and Olcott[13] have shown that the ankle pressures obtained 1 minute after a 5-minute treadmill exercise are roughly equivalent to those obtained 30 seconds after the lesser degree of hyperemia induced by an equal duration of suprasystolic thigh cuff occlusion. Repeated dorsiflexion of an elevated limb was significantly less effective than either in producing a pressure drop. Therefore, the former two are acceptable as equivalent stress tests, although treadmill exercise is preferred. Walking for 5 minutes at a treadmill speed of 2 mph (176 ft/min) is roughly equivalent to walking three blocks (900 ft) at average speed.

The term *"ischemic rest pain"* has been well characterized by Cranley[14] and indicates diffuse pedal ischemia. It is a severe pain not readily controlled by analgesics that is localized to the forefoot and toes or, if more proximal, includes these distal parts. It may also be localized to the vicinity of focal ischemic lesions. It is brought on or made worse by elevation and relieved by dependency and therefore is often only experienced at night or when lying down. Diffuse pedal ischemia with ischemic rest pain is commonly associated with ankle pressures *lower than* 40 mm Hg and toe pressures *lower than* 30 mm Hg.

"Gangrene" may be *focal,* as in the case of focal arterial thrombosis or atherothrombotic microembolism, where there is still adequate perfusion of adjacent tissues to allow successful auto- or local surgical amputation. Such focal gangrene may therefore not be associated with diffuse pedal ischemia and ischemic rest pain. Gangrene associated with diffuse pedal ischemia will not allow successful management by local measures alone (i.e., will at least require pharmacotherapy and usually a revascularization procedure to allow debridement/amputation to heal) and is almost invariably associated with typical ischemic rest pain.

Ulcers in distal parts of the extremity may be caused or perpetuated by a number of etiologic factors, each with its own distinguishing characteristics

(e.g., pressure, venous insufficiency, trauma, diabetic, or other neuropathies), as well as by persistent arterial insufficiency. The term "nonhealing ischemic ulcer" implies that, regardless of initial cause, there is insufficient arterial perfusion to support the inflammatory response required for healing. Associated with this, there is usually ischemic rest pain and objective evidence of diffuse pedal ischemia, for example, critical reductions in the ankle or toe pressures, a flat or barely pulsatile plethysmographic tracing at the ankle or transmetatarsal level, a reduced cutaneous oxygen level, or the lack of an inflammatory response as gauged by radionuclide studies.[15-19] An ankle pressure upper limit of 60 mm Hg is recommended for this category rather than 40 mm Hg. Similarly, a toe pressure of 40 mm Hg is recommended for this category, instead of the 30 mm Hg suggested for rest pain. These higher pressures recognize the additional perfusion that is required to heal an ulcer or a distal amputation, especially if secondary infection is present. The other tests mentioned above may be useful to gauge local healing, particularly in patients with diabetes in whom ankle pressures may be unreliable or absent, or when lesions on the great toe preclude toe pressure measurement. However, they have either have too wide a range of values for predicting healing or have not been correlated predictably with ischemic rest pain. For example, a TcO2 of 30 mm Hg is conveniently equivalent to a toe pressure of 30 mm Hg in predicting healing, but there is a significant range between no healing (<20 mm Hg) and reliable prediction of healing (>40 mm Hg), and it has not been well correlated with the onset of rest pain. Therefore, neither it nor the other tests are currently recommended as a stand-alone criteria for categorizing levels of chronic ischemia.

COMMENT: The pressure levels selected above are admittedly arbitrary, and it is recognized that no single level can cleanly separate categories, but they have a rational basis. The European Consensus on Critical Ischemia[20] selected a common pressure level (50 mm Hg ankle and 30 mm Hg toe pressure) to define *both* Fontaine classes III and IV, equivalent to our grades II and III and categories 4, 5, and 6 *inclusively.* Using the same criteria both for those with rest pain and for those with tissue loss may be simpler, but it does not recognize the difference between the level of perfusion pressure required to preserve intact tissue and stave off ischemic rest pain on the one hand and the additional circulatory requirement for healing ischemic foot lesions on the other.

Others have recommended an ABI rather than an ankle pressure to define these advanced levels of ischemia. However, absolute pressure levels are better for defining levels of chronic ischemia because it is the actual perfusion pressure that is critical. A given ABI can represent a wide range of ankle pressures, for example, the difference in ankle pressure between two patients with an ABI of 0.30 but with systolic blood pressures of 110 and 160 is 15 mm Hg (33 mm Hg compared with 48 mm Hg), an almost 50% difference, with a likelihood of ischemic pain only in the former. However, pressure indexes such as the ABI are better for comparing groups of patients, as well as monitoring a given patient over different points in time, for example, after bypass surgery.

The term *"limb salvage"* is a misnomer and often loosely applied. It is commonly applied to indicate salvage of the foot, not the limb, and this is retrospectively determined, yet the term is often applied prospectively. It might be best abandoned, but clinicians are likely to continue to use it. "Chronic critical ischemia," as first defined by Jamieson et al.[15] and as developed by a European Consensus Group chaired by Dormandy,[20] is a more apt term. The presence of rest pain, nonhealing ulceration, or gangrene *plus* objective evidence of diffuse pedal ischemia, as defined earlier (i.e. grades II and III and categories 4, 5, and 6 in Table II), qualify the patient for such categorization. Rest pain, in the absence of frank tissue loss, should persist at a level that requires moderate to strong analgesia for at least 3 weeks before such designation.

The term *chronic "subcritical" ischemia* has been suggested for a particular subgroup that falls between the definitions of claudication and chronic *critical* ischemia. Typically, these patients have levels of perfusion pressure between that required for healing (e.g., 60 mm Hg) and that commonly associated with ischemic rest pain (e.g., 40 mm Hg). If sedentary, they may not have claudication, and they have no rest pain or tissue loss. In this asymptomatic no-man's-land, an apparent category 0, they are nevertheless quite vulnerable and could not heal a foot lesion if one was precipitated by minor trauma, resulting in an immediate drop to category 5. They, like patients with claudication in this lower pressure strata, have a higher risk of ultimate limb loss than those at higher levels.[7-12]

Qualification for the designation "limb salvage." The term "limb salvage" should not be applied to *patients* with critical ischemia, but only to therapeutic outcome and to *operations* or other interventions that are intended to avoid an otherwise

inevitable *major* amputation. Although an *unexpected* minor amputation after a revascularization procedure performed on an intact limb constitutes a major complication and a treatment failure, a revascularization procedure in a patient with established tissue loss, which allows a minor amputation to heal, would qualify as a success, and thus a limb salvage procedure. In this regard, minor and major amputation needs to be defined. The designation "minor amputation" requires retention of a sufficiently functional foot remnant to allow standing and walking *without a prosthesis.* A modified shoe is allowable, but a Syme's amputation, because it involves shortening and prosthetic fitting, would not qualify as a minor amputation and inclusion under the term "limb salvage." Therefore, minor amputation will be represented for the most part by toe or transmetatarsal amputations, with Syme's and most high forefoot amputations (e.g., Chopart's) being included under "major amputations." Revascularization that allows healing of a below-knee amputation when above-knee amputation would have been otherwise predicted, although in a sense representing partial limb salvage, does *not* qualify under the designation "limb salvage" in these reporting standards. Finally, in studies that involve the treatment of ischemic ulcers, complete and lasting healing should be demonstrated for inclusion under the designation of limb salvage. Reduction in ulcer area is a permissible end point only in drug trials of short duration.

Other categorization recommendations. Operations for microembolism or "blue toe syndrome," although often justified to save the foot from eventual partial or complete loss after recurrent embolization, *do not* qualify for inclusion with "limb salvage operations," *unless* there is objective evidence of *diffuse* pedal ischemia, a visible threat of tissue loss (i.e., chronic critical ischemia), *and* a proximal hemodynamically significant obstructive lesion is corrected or bypassed. Because of their uniqueness, such cases are better reported separately. If included in overall reviews of experiences with arterial reconstructions, *those without diffuse pedal ischemia* should be listed with other hemodynamically insignificant lesions (grade or category 0) along with graft structural defects or false aneurysms, unless they are associated with a significant enough occlusive lesion to cause claudication (grade I, categories 1 to 3). The same rules apply to graft or anastomotic stenoses that are detected by surveillance programs. Finally, it is recommended that the relative portion (%) of nonhealing ulcers and gangrene be indicated in reporting on those with actual tissue loss (i.e., in category 5).

OUTCOME CRITERIA

Outcome after treatment of peripheral arterial occlusive disease can be gauged by a number of parameters—some reflecting success, others reflecting failure. In the literature, such terms as "technical success," "anatomic or angiographic success," "clinical success," and "hemodynamic success" have been used in early assessment, particularly after endovascular procedures, whereas patency, limb salvage, and continued clinical improvement are terms more commonly applied to late follow-up status. It is desirable to reduce these outcome criteria to those that have significant value and to apply precise and uniform definitions to them. In addition, it is valuable for comparative purposes to be able to gauge *the degree of change* in clinical status in relation to the pretreatment assessment. This would allow clinical success or failure over time to be reported in uniform and objective terms. A scheme for this will be presented along with guidelines for assessing hemodynamic success or failure and patency.

Criteria for reporting significant change in clinical status

Clinical assessment, when expressed in terms of "symptomatic relief," has been notoriously unreliable in the past because it lacked objectivity. Combining standard clinical categories (as previously defined) with objective noninvasive testing (as described below) can overcome this weakness. For reporting purposes, the designation "clinically improved" requires an upward shift by at least one clinical category (as defined earlier and summarized in Table II) except for those with actual tissue loss (category 5), who must move up at least two categories and at least reach a level of claudication to be considered improved. In addition, to claim cause and effect and attribute the improvement to the treatment, some objective evidence of hemodynamic change needs to be included when revascularization procedures (as opposed to exercise or drug therapy) are being evaluated or compared, and here a change in the ABI of more than 0.10 is recommended. In patients in whom the ABI can not be accurately measured (e.g., patients with diabetes and rigid calcified arteries), the toe pressure, which is usually unaffected by this, or any measurable pressure distal to the revascularization may be substituted. The scale shown in Table III details this recommended approach for gauging the degree of improvement or worsening in individual patients. For group comparisons, the percent of patients who have "significantly

Table III. Recommended scale for gauging changes in clinical status

+3	*Markedly improved: No* ischemic symptoms, and any foot lesions completely healed; ABI essentially "normalized" (increased to more than 0.90)
+2	*Moderately improved:* No open foot lesions; still symptomatic but only with exercise *and* improved by at least one category*; ABI not normalized but increased by more than 0.10
+1	*Minimally improved:* Greater than 0.10 increase in ABI† but no categorical improvement *or* vice versa (i.e., upward categorical shift without an increase in ABI of more than 0.10)
0	*No change:* No categorical shift and less than 0.10 change in ABI
−1	*Mildly worse:* No categorical shift but ABI decreased more than 0.10, or downward categorical shift with ABI decrease less than 0.10
−2	*Moderately worse:* One category worse or unexpected minor amputation
−3	*Markedly worse:* More than one category worse or unexpected major amputations

*Categories refer to clinical classification (Table II).
†In cases where the ABI cannot be accurately measured, an index based on the toe pressure, or any measurable pressure distal to the site of revascularization, may be substituted.

improved" (i.e., either +2 or +3) can then be compared.

COMMENT: Gauging the degree of clinical change is the primary goal of this grading scale. The use of an ABI change of 0.10 here is not intended as indirect evidence of patency but as the *least* acceptable evidence of hemodynamic improvement, to guard against the fallibility of basing success on symptomatic improvement alone. It will be noted that, in attempting to provide an objective basis for claiming "improvement" here, and later for defining "hemodynamic success" or "failure" and for supporting a claim of patency, an ABI change of 0.10 has been chosen. In an earlier study, Carter[21] recommended 0.15 as the minimum requirement for significant change. This was widely accepted, and many vascular surgeons still prefer this. However, the ad hoc committee that originally developed these standards believed that a difference of 0.10 was sufficient to signify true change, *if combined with categorical clinical improvement,* as required. It was thought that 0.15 was too strict and might unfairly exclude patients who truly benefitted. For example, using a 0.15 increase as a requirement would categorize as a failure a patient with a blood pressure of 120, whose ankle pressure increased after treatment from 24 to 41 mm Hg (from 0.20 to 0.34 ABI), even though such a patient would likely be relieved of rest pain. Similarly, a patient relieved of claudication by iliac percutaneous transluminal angioplasty (PTA) with an ABI increased from 0.86 to 1.00 would be considered a failure if a 0.15 ABI increase were required. Thus the original recommendation has been retained.

Hemodynamic success or failure. The term "hemodynamic failure" has been used to indicate a lack of significant hemodynamic improvement (i.e., an increase in ABI) in spite of a patent revascularization. The common setting for this is multilevel disease where a proximal reconstruction is performed in the face of residual distal disease or "poor runoff." It can also be seen after PTA where dissection or elastic recoil of an unyielding plaque may result in incomplete restoration of luminal diameter (although this can also be considered a form of technical failure). Again, for the sake of uniformity, a specific degree of change must be recommended, and for reasons given above an increase of less than 0.10 in the *distal* pressure index constitutes a hemodynamic failure. Thus in the specific circumstance of a proximal or inflow procedure (e.g., femorofemoral bypass or iliac PTA) being performed in the face of outflow disease or poor runoff (e.g., superficial femoral artery occlusion), failure to increase the ABI by at least 0.10 is considered a *hemodynamic failure.* Conversely, increasing the ABI by more than 0.10 can be considered a "hemodynamic success," but it would not be considered a "clinical success" without *categorical* clinical improvement, as described earlier.

Criteria for patency. Articles in scientific journals should only accept patency rates that are based on objective findings. A bypass graft or otherwise reconstructed arterial segment may be considered patent when one of the following five criteria is met. Beyond the last date of such proof of patency, they must be considered lost to follow-up.

1. Demonstrably patent graft by an accepted vascular imaging technique, such as arteriography, Duplex ultrasound color-flow scan, or magnetic resonance imaging.
2. The presence of a palpable pulse, or the recording of a biphasic or triphasic Doppler wave form at *two* points directly over a *superficially* placed graft.

3. Maintenance of the achieved improvement in the *appropriate* segmental limb pressure index, that is, not more than 0.10 below the highest postoperative index. Although a greater reduction in pressure index may occur and the graft or reopened segment may still be patent, *imaging proof is required in these instances or any other doubtful or marginal circumstances covered under criteria 2, 3, or 4.* To avoid the confusing effects of distal runoff disease, the most appropriate pressure index for this purpose is at the next level beyond the revascularized segment or distal anastomosis (see comment below).
4. Maintenance of a plethysmographic tracing distal to the reconstruction that is at least 50% or 5 mm greater in magnitude than the preoperative value and close to the postoperative value. (This is the weakest criterion and acceptable *only* when accurate pressures cannot be measured, as with calcific arteritis in a diabetic patient. However, even in such cases, stronger evidence of patency, in the form of imaging, is clearly preferred.)
5. Direct observation of patency at operation or postmortem examination.

COMMENT: Although palpable pedal pulses that are readily felt by an experienced observer are adequate for routine clinical assessment, such observations (and particularly comments to this effect in the patient's record by nurses, residents, or fellows) cannot be accepted as proof of patency for reports in scientific journals. *Accurate patency data are so crucial to comparisons of arterial reconstructive techniques that reliable objective methods must be used.* Duplex or color-flow Doppler scanning is now an accepted and commonly used method of graft surveillance and should be available in most centers. Failing this, Doppler measurement of ankle and brachial pressures can be used. At the time of the original Standards, before color-flow duplex scanning was widely available, the use of Doppler-derived pressure measurements was a reasonable expediency because angiographic follow-up was impractical. It allowed investigators to claim patency in the absence of other documentation, using retrospective vascular laboratory data. Now, the debate over the significance of a 0.10 versus 0.15 change in ABI has been tempered by the duplex scan, which can and should be used to settle the issue of patency in equivocal cases.

At this point, it is worth reemphasizing that the designation of *"clinically improved"* is based on categorical clinical improvement *plus* objective evidence of hemodynamic improvement (i.e., the ABI). *Hemodynamic success,* or conversely *hemodynamic failure,* also applies to the entire limb and therefore also uses a distal monitoring site (i.e., the ABI). In contrast, *patency* applies to the revascularized or bypassed segment only, and if imaging studies or direct observation are not available, one should use the pressure index *from the next level beyond that segment* (e.g., the thigh-brachial index rather than the ABI for a proximal bypass graft or PTA). This is recommended to avoid the confusing effects of new or progressing occlusive disease between the revascularized segment and the point of pressure monitoring.

Failed and failing grafts. A graft that has lost its patency—that is, has thrombosed—is considered a "failed" graft. This is in contrast to a "failing" graft, a graft that is still demonstrably patent but that has developed one or more stenoses that, if unrelieved, may lead to thrombosis. Such lesions may or may not produce symptoms or a significant drop in the resting ABI but can be detected by duplex surveillance of the graft and its anastomoses. Furthermore, their correction significantly improves assisted primary and secondary patency rates,[22] as defined below. Diagnostic criteria include a peak systolic velocity in the stenosis that is greater than a certain level (e.g., 150 cm/sec) or is significantly greater than (e.g., at least 2.5 times) that of an adjacent "normal" segment.[23] With greater degrees of stenosis, the end diastolic velocity in the stenosis usually becomes similarly elevated and the ratio of accelerated to background velocity climbs.[24] Failure has also been predicted by an overall reduction in graft flow velocity below 45 cm/sec,[24] but this criterion applies mainly to femoropopliteal *vein* grafts, not tibial bypass grafts or those that using a prosthetic bypass graft. The specific criteria used are not yet standardized and differ somewhat from center to center. Their accuracy in predicting *the actual degree* of stenosis (e.g., >50% versus >75%) is also not well established, nor is the degree of stenosis beyond which failure is inevitable. Therefore, confirmatory arteriography is usually deemed necessary before intervening. Nevertheless, the concept and definition of a failing graft has gained wide acceptance and deserves inclusion in these reporting standards. Until standard diagnostic criteria are accepted, reports on this aspect should include the duplex criteria used, angiographic confirmation, or both.

Patency status: primary vs secondary patency. With the help of graft thrombectomy or thrombolysis, revision or "redo," it may be claimed that the original graft is still patent. It is important in this regard to separate "primary" from "secondary" patency. A graft is considered to have "primary" pa-

tency if it has had *uninterrupted* patency with *either* no procedure performed on it *or* a procedure (e.g., transluminal dilation or a proximal or distal extension to the graft) to deal with disease progression *in the adjacent native vessel.* Thus the only exceptions that do *not* disqualify the graft for primary patency are procedures performed for disease *beyond* the graft and its two anastomoses. Dilations or minor revisions performed for stenoses, dilations, or other structural defects, or closing missed arteriovenous fistulas in an in situ vein bypass graft *before* occlusion do *not* constitute exceptions, as they are intended to prevent eventual graft failure.

When originally proposed,[1] considerable objections were raised against this last rule governing primary patency,[25] understandably, because bypass grafts that never occluded but underwent minor procedures to protect patency were considered the same as those that had actually thrombosed, that is, they were all listed as secondary patency data. Ultimately, the additional designation of "assisted primary patency" was suggested to apply to this situation, in which patency was never lost but maintained by prophylactic intervention.[26] This has proven useful and is included in this revised version.

If graft patency is restored *after* occlusion by thrombectomy, thrombolysis, or transluminal angioplasty, and/or any problems with the graft itself or one of its anastomoses require revision or reconstruction, *all* must be listed under "secondary" patency. A "redo" or secondary reconstruction, as defined later, does *not* contribute to secondary patency *unless most of the original graft and at least one anastomosis are retained in continuity.*

It should be understood that both primary and secondary patency rates are important. The former is important in judging the natural history of a graft or reconstructive procedure, and the latter is important to indicate how long function can be preserved with the aid of close surveillance and the use of secondary or adjunctive procedures. Both provide valuable information, but when only one or the other patency rate is presented and one is not identified, comparison between different reports on the same type of reconstructive procedure is difficult, if not impossible. Therefore, it is recommended that in each report, *both* primary and secondary patency rates be presented, and the patency rate under discussion is identified as primary or secondary. The same applies to the assisted primary patency rate, should it be used. Thus it is appropriate, in analyzing an experience with extremity bypass or in comparing two such procedures where a program of graft surveillance and intervention for preservation of patency is used, to present all three patency rates to demonstrate the intrinsic durability of the primary procedure, the impact of graft surveillance and prophylactic intervention, and the ability to restore function to a failed graft.

It has been suggested that secondary reconstructions that do not qualify under the definition of secondary patency be allowed to contribute to "tertiary patency," that is, patency across the same limb segment achieved by one or more additional procedures that do not preserve, in continuity, most of the original graft and one anastomosis. Although this adds some perspective regarding the ultimate status of the limb, and such procedures do contribute to limb salvage and function, this is *not* a recommended reporting standard. It only gauges the overall success of surgical management and not the merits of the original bypass or revascularization procedure, which is the primary focus of patency analysis.

Estimating patency rates. Although subject to some artifact, so that projected and actual patency rates are not necessarily the same, the life table (LT) method is one of the best and most commonly used ways of presenting patency data on patients who undergo a revascularization procedure at different points in time and are followed-up for different lengths of time. Only the LT method was recommended for this purpose in our original standards.[1] It is still an accepted method *if* its rules are followed, but its limitations must be appreciated. The Kaplan-Meier survival estimate is an equally acceptable method under most circumstances. Both of these methods are described and compared in the following paragraphs.

The LT method was best characterized by Peto et al.[27,28] in 1976 and 1977 in two articles in the *British Journal of Cancer,* but such methods were earlier described by Berkson and Gage in 1950[29] and also by Cutler and Ederer in 1958.[30] It was originally applied to the follow-up data of patients with different forms of cancer and cancer therapy. The LT method has two features that characterize the technique. The first is that events on the survival curve—for example, graft failures—are grouped into intervals. Survival rates are then calculated for each of these intervals and are used to generate cumulative patency rates that describe the survival curve. The second important feature is the assumption that any individuals lost to follow-up during an interval (also called censored data) are treated as withdrawn at the *midpoint* of the interval. It is this assumption that

Table IV. Life table example

A	*B*	*C*	*D*	*E*	*F*	*G*
Interval (mo)	*No. at risk at beginning of interval*	*No. failed during interval*	*Withdrawn during interval*	*Interval failure rate*	*Cumulative patency rate*	*Standard error*
0 to 6	64	3	2	0.048	95.2%	2.60%
6 to 12	59	10	0	0.169	79.1%	4.71%
12 to 18	49	5	0	0.102	71.0%	5.46%
18 to 24	44	4	0	0.091	64.6%	5.79%
24 to 30	40	2	1	0.051	61.3%	6.03%
30 to 36	37	3	5	0.087	56.0%	6.11%
36 to 42	29	1	2	0.036	54.0%	6.80%
42 to 48	26	0	4	0.000	54.0%	7.18%
48 to 54	22	0	4	0.000	54.0%	7.81%
54 to 60	18	1	1	0.057	50.9%	8.41%
60 to 66	16	0	3	0.000	50.9%	8.92%
66 to 72	13	0	10	0.000	50.9%	9.89%
72 to 76	3	0	3	0.000	50.9%	20.59%

Column E = C / (B − ½D).
Column F = (1 − column E) × previous interval's cumulative patency rate.
Column G = F × $\sqrt{(1 - [F / 100])} / C$.

leads to the characteristic correction to the calculated failure rate for a given interval:

$$\text{Failure rate} = \frac{\text{Number of failures}}{\text{Number at risk} - \frac{1}{2}\,\text{Number of withdrawals}}$$

This correction considers the individuals who were withdrawn to contribute to the risk pool for only half of the interval. However, this correction is *mathematically equivalent* to increasing the interval failure rate by the number of expected failures in half of the withdrawal group:

$$\text{Failure rate} = \frac{\text{Number of failures}}{\text{Number at risk}} + \text{Failure rate} \times \frac{1}{2}\,\text{Number of Withdrawals}$$

The further consequence of this correction for censored data or withdrawals is that the failure rate is assumed to be uniform over the interval. With this in mind, the use of the stair-step graphical presentation of the LT plot is not strictly necessary because the cumulative patency rate is the resulting conditional probability at the *end* of the interval based on the failure rate over the entire interval. The LT graph can thus be represented by straight line connections between the patency estimates located at the *end* of each interval. In this presentation, the only intervals with level lines are those with no failures.

LT analysis should include the following columns in the table (alphabetically listed as in the example presented in Table IV): (A) intervals in months; (B) number of grafts at risk at the start of the interval; (C) number failed during the interval; (D) number of patients withdrawn with patent grafts during the interval, due to death, loss to follow-up, or with follow-up that ends during that time interval (these three may be tabulated in separate columns, then combined); (E) interval failure rate; (F) cumulative patency rate; and (G) standard error. Cumulative mortality data, though not a requisite part of the LT, add perspective and may be included in an additional column for that reason.

The following paragraph summarizes, as simply as possible, the determination and serial calculation of each of the columns in the LT. Calculations may be followed by referring again to the example presented in Table IV. (A) *Interval in months* can be chosen to represent any desired time span shorter than the review period, and they need not be equal. It is useful to have the first interval as 0 to 1 month to show early patency, and 3- to 6-month intervals are commonly chosen thereafter. More frequent intervals increase precision. (B) *Number of grafts at risk at start* in the first interval are the number entered into the study, and in subsequent intervals are derived by subtracting columns C and D from B in the previous interval. (C) *Number of grafts failed* are those that had known occlusion occurring during this interval. (D) *Number of grafts withdrawn:* patients with patent grafts in the previous interval who died or were lost to follow-up during the interval or did not complete the present interval. (E) *Interval patency* is calculated as 1 − interval failure rate, which is in turn

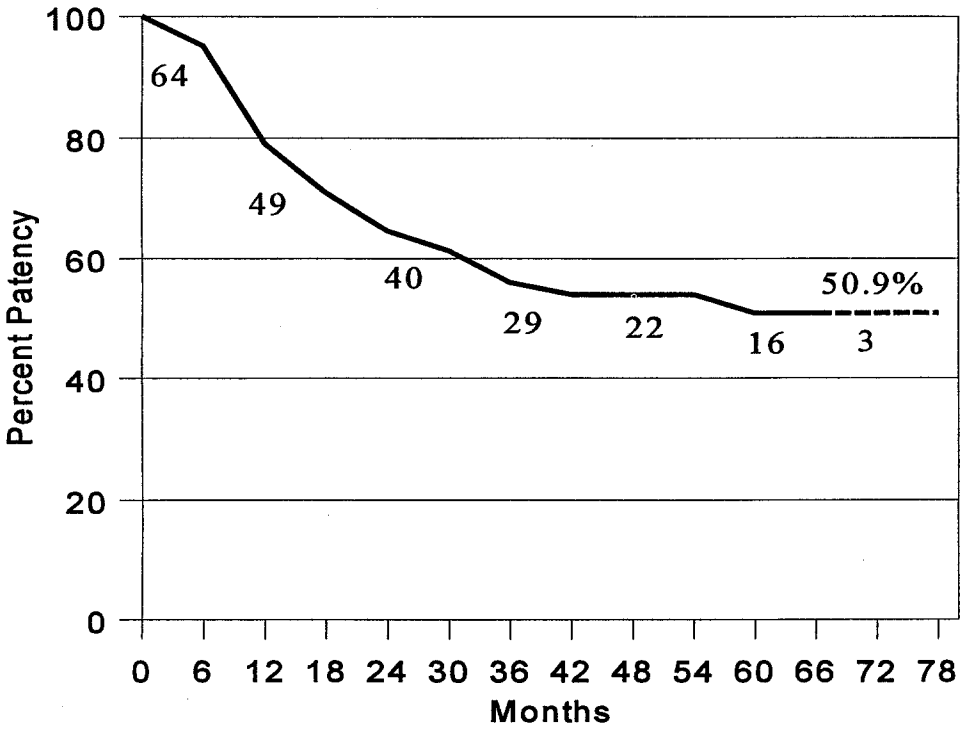

Fig. 1. Patency curve by life table method (data in Table IV).

calculated by dividing column C by (column B minus half of column D), according to the theoretical considerations given above. (F) *The cumulative patency rate* is 100% for the first interval, and for each successive interval is obtained by multiplying the present interval patency rate by the cumulative patency rate in the previous period. (G) *Standard errors* in percent are calculated as 100 × F × square root of (1 − F)/B, where F equals the cumulative patency rate and B the number at risk at the start of the interval.

An equally appropriate alternative method for estimating patency is the Kaplan-Meier survival estimate (KM),[31] which is also called the product-limit method. The KM estimate is different from the LT method in that data are *not* grouped into intervals. Events on the survival curve occur only at individual failure points. No assumptions are made about the failure rate of withdrawals. In contrast to the LT method, graphical presentation of the KM survival curve *should* use the stair-step method because, between events on the KM curve, nothing is known or assumed about the failure rate. One can conceptualize the KM method as an LT method with small intervals containing a single event. The same data are presented in Table IV and Fig. 1 for LT analysis and Table V and Fig. 2 for analysis by the KM method. The final endpoints are almost identical.

The LT method makes calculations easier for very large amounts of data, and this may be the main justification for using it rather than the KM. However, vascular patency studies do not usually have prohibitively large data sets, and such considerations have become almost moot with the advent of desktop computers. Indeed, the LT method is not strictly valid for numbers less than 30, whereas the KM method remains appropriate for any data size.[32] Either method is acceptable if properly used and documented. The data shown in Figs. 1 and 2 were comparatively tested by adding a number of early patent cases ("front loading") and by subtracting an equal number of early withdrawals, and in each instance the late patency rates were still roughly equivalent.

Complete LT or KM data should be submitted as a table with each report, to allow the validity of the data to be checked, even though it may be the choice of the editor only to publish the graph. Numbers for the patients at risk at the start of each interval (periodically for the KM) *or* the standard error for each estimate of patency must be displayed using bars. When comparing multiple curves or plots in a single figure, these bars may clutter the graph or figure. Pointing the bars in opposite directions or using bars at selected rather than all intervals will usually obviate

Table V. Kaplan-Meier example

A	*B*	*C*	*D*	*E*	*F*	*G*
Event time (mo)	*No. at risk at event*	*No. of events*	*Withdrawn*	*Failure rate*	*Cumulative patency rate*	*Standard error*
2.5	64	1	0	0.016	98.4%	1.54%
3.2	63	0	1	0.000	98.4%	1.55%
4.1	62	1	0	0.016	96.8%	2.18%
4.4	61	0	1	0.000	96.8%	2.20%
4.6	60	1	0	0.017	95.2%	2.68%
6.2	59	1	0	0.017	93.6%	3.08%
6.4	58	1	0	0.017	92.0%	3.42%
*	*	*	*	*	*	*
70.9	4	0	1	0.000	50.7%	17.79%
71.5	3	0	1	0.000	50.7%	20.55%
75.3	2	0	1	0.000	50.7%	25.17%
75.7	1	0	1	0.000	50.7%	35.59%

*The mid-portion of the table has been omitted for brevity.
Column E = C / B
Column F = (1 − column E) × previous interval's cumulative patency rate.
Column G = F × $\sqrt{(1 - [F / 100]) / C}$

this clutter. When the standard error of the patency rate estimate exceeds 10%, the curve either should not be drawn or should be represented by a dotted line as a means of indicating lack of reliability of the estimate. Comparisons of patency curves should be performed using the log-rank test of significance.[33]

Whenever possible, separate LTs should be provided for each type of operative procedure. Generally, one should not mix data from several different levels of infrainguinal bypass grafts but report separately above-knee femoropopliteal bypass grafts, below-knee femoropopliteal bypass grafts, and femoral infrapopliteal bypass grafts, for example. Where pertinent, *specifically where differences are claimed,* additional LT or KM plots should be reported for different indications for operation (e.g., claudication vs foot salvage), for different runoff status, or for any major risk or treatment factors that appear to affect patency (e.g., with and without antiplatelet therapy, or diabetic vs nondiabetic), particularly if they are claimed to do so. In some instances, interdependence of variables will limit the confidence with which conclusions may be drawn from this subgrouping of data. In this situation, it is often appropriate to apply multivariate analysis using the Cox hazard regression analysis.[34]

COMMENT: It is not uncommon for authors who report on revascularization procedures to acknowledge an initial failure rate but then exclude such failures from the calculation of cumulative patency rates. Although information is not withheld, the practice is deceiving. For example, if 25% of a particular intervention initially failed but 80% of those successful were still patent after a given time period, only 60% of those initially treated will have benefitted. Similarly, with such an initial failure rate, if two thirds of successful grafts remained patent, less than half would have benefitted. This "intent to treat" rule may occasionally seem too strict, as in a patient in whom a bypass procedure is canceled because of a myocardial infarction suffered during induction of anesthesia, or when there is inability to gain percutaneous access for introduction of a caval filter. However, to arbitrarily allow such "reasonable" variances would create more problems than it would solve, and therefore the "intent to treat" rule has been retained.

IDENTIFYING AND GRADING FACTORS THAT MODIFY OUTCOME

Clinical reports that evaluate revascularization procedures, particularly those that compare different treatment methods, may be difficult to interpret when differences in factors that can affect outcome are not identified and characterized. For example, for infrainguinal bypass procedures, diabetes, tobacco usage, and occlusive disease distal to the revascularization ("runoff") may affect patency rates and the degree of improvement, whereas cardiac, pulmonary, and renal status may influence operative mortality rates and long-term survival rates. Grading such factors in severity, with uniform definitions for (1) mild, (2) moderate, and (3) severe, would allow severity indices to be calculated for intergroup comparison.[35] The following simplified grading system is offered for common risk factors, recognizing that other alterna-

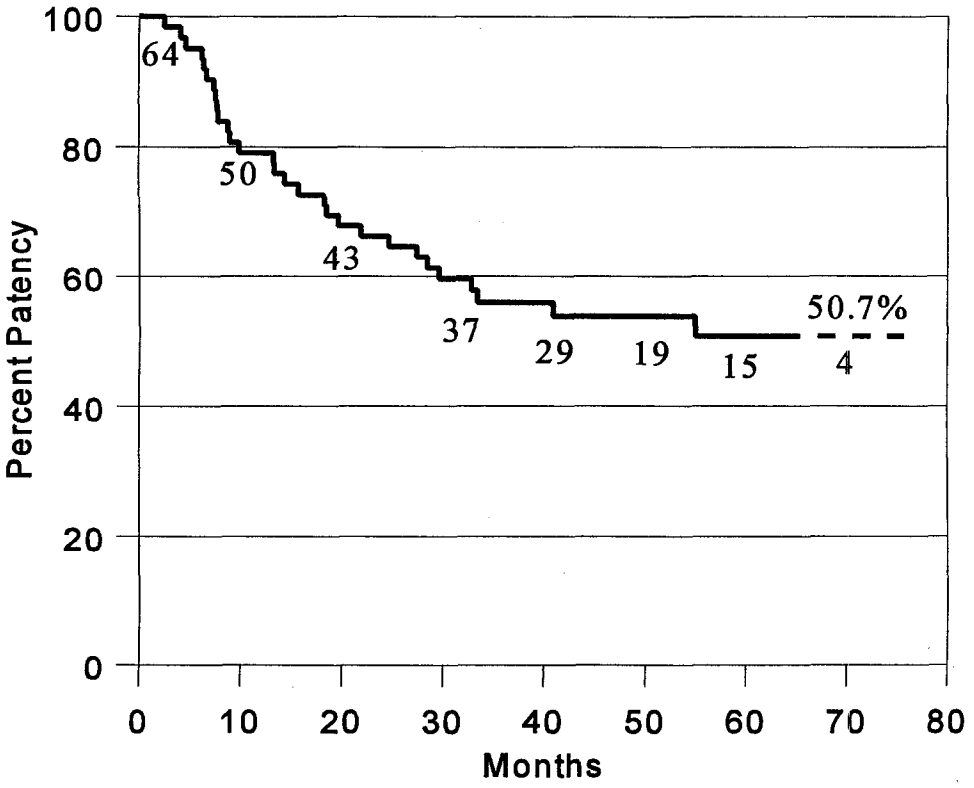

Fig. 2. Kaplan-Meier patency curve (data in Table V).

tive schemes may have been proposed but none has gained universal acceptance. A scheme for grading "runoff" is also proposed.

Diabetes: 0 = none; 1 = adult onset, controlled by diet or oral agents; 2 = adult onset, insulin-controlled; 3 = juvenile onset.

Tobacco use: 0 = none or none for last 10 years; 1 = none current, but smoked in last 10 years; 2 = current (includes abstinence less than 1 year), less than 1 pack/day; 3 = current, greater than 1 pack/day.

Hypertension: 0 = none (cutoff point, diastolic pressure usually lower than 90 mm Hg); 1 = controlled (cutoff point, diastolic pressure usually lower than 90 mm Hg) with single drug; 2 = controlled with two drugs; 3 = requires more than two drugs or is uncontrolled.

Hyperlipemia: 0 = cholesterol (low-density lipoprotein and total) and triglyceride levels within normal limits for age; 1 = mild elevation, readily controllable by diet; 2 = moderate elevation requiring strict dietary control; 3 = same as 2, but severe enough to require dietary *and* drug control.

Cardiac status: 0 = *asymptomatic,* with normal electrocardiogram; 1 = *asymptomatic* but with either remote myocardial infarction by history (>6 months), occult myocardial infarction by electrocardiogram, or *fixed* defect on dipyridamole thallium or similar scan; 2 = any one of the following: stable angina, no angina but significant *reversible* perfusion defect on dipyridamole thallium scan, significant silent ischemia (≥1% of time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, history of congestive heart failure that is now well compensated; 3 = any one of the following: unstable angina, symptomatic or poorly controlled ectopy/arrhythmia (chronic/recurrent), poorly compensated or recurrent congestive heart failure, ejection fraction less than 25%, myocardial infarction within 6 months.

Carotid disease: 0 = no symptoms, no evidence of disease; 1 = *asymptomatic* but with evidence of disease determined by duplex scan or other accepted noninvasive test or arteriogram; 2 = transient or temporary stroke; 3 = completed stroke with permanent neurologic deficit or acute stroke.

Renal status: (refers to stable levels, not transient drops or elevations in response to intravenous medication, hydration, or contrast media) 0 = no known renal disease, normal serum creatinine level; 1 =

moderately elevated creatinine level, as high as 2.4 mg/dl; 2 = creatinine level, 2.5 to 5.9 mg/dl; 3 = creatinine level greater than 6.0 mg/dl, or on dialysis or with kidney transplant.

Pulmonary status: 0 = asymptomatic, normal chest x-ray film, pulmonary function tests within 20% of predicted; 1 = asymptomatic or mild dyspnea on exertion, mild chronic parenchymal x-ray changes, pulmonary function tests 65% to 80% of predicted; 2 = between 1 and 3; 3 = vital capacity less than 1.85 L, FEV_1 less than 1.2 L or less than 35% of predicted, maximal voluntary ventilation less than 50% of predicted, Pco_2 greater than 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension.

COMMENT: Goldman's cardiac risk index is not recommended, even though it combines nine independent factors that correlate with life-threatening and fatal complications,[36] because it has been shown *not* to correlate with cardiac events in vascular surgery patients, presumably because their more sedentary lifestyle masks some of the evidence of cardiac disease.[37] Cardiac screening tests, or even the results of coronary angiography, offer acceptable alternative information for stratifying patients' cardiac risk, but their routine application to all vascular surgery patients can not be justified at this time. Eagle et al.[38,39] has identified five risk factors for coronary disease (age more than 70 years, diabetes, history or electrocardiographic evidence of myocardial infarction, angina, and congestive heart failure) that, when used in combination, allow the *selective* application of cardiac screening tests and, in turn, lead to stratification of risk of perioperative cardiac ischemic events. Such an approach has proven acceptable for reports on aortic aneurysm surgery but is, as yet, unproven in patients with limb ischemia.[38,39] In the absence of a proven scheme for stratifying the cardiac risk of patients who undergo vascular surgery, the original cardiac risk score has been modified to include both clinical information and the results of cardiac screening tests.

It is understood that it will not be appropriate, or feasible, to include *all* of the above risk factors in each report. Nevertheless, reports that *claim* improved patency rates, decreased early or late mortality rates, or fewer pulmonary complications, for example, should support their claim by including standardized information on appropriate risk factors. It should be apparent that risk factors that affect mortality rates are not identical with those that relate to patency. For example, cardiac status dominates mortality risk, with pulmonary and renal status also contributing to a degree. For patency and limb salvage rates, or other measures of long-term success of revascularization procedures, smoking, diabetes, and renal status, as well as severity of runoff disease (see below) commonly correlate with outcome, as does hyperlipidemia to a lesser degree.

Runoff. It is understood that no scheme for grading runoff is perfect, is likely to be universally accepted, or will always correlate with early or late graft failure. Nevertheless, a grading scheme that provides a reasonable degree of correlation with outcome is desirable. Simpler (good/poor or 1 to 4) grading schemes have been used in the past, mainly for gauging the outcome of femoropopliteal bypass grafting. The one proposed here holds the advantage that it may be applied to any level of distal anastomosis rather than just to femoropopliteal bypass grafts. Since its introduction, this scheme has been tested by correlation against patency in numerous reports, with mixed results. In general, it has not correlated as well with the patency of infrainguinal vein grafts (where patency rates are usually good despite compromise runoff) as it has with infrainguinal bypass procedures performed with grafts other than greater saphenous vein. The previous version[1] did not sufficiently accommodate pedal artery/arch patency, which, now that excellent runoff visualization is being regularly obtained and pedal bypasses are common, is clearly needed. Finally, problems have arisen when infrainguinal bypass grafts with different levels of distal anastomosis have been mixed together or compared. For example, a bypass graft to a popliteal artery with single tibial artery runoff (runoff score, 7) is not comparable to a bypass graft to a patent tibial artery (runoff score, 1), even though the outflow to the foot is identical. Therefore, it should be understood that this runoff scheme is useful for comparing bypass grafts *grouped according to the level of distal anastomosis,* for example, femoral or popliteal or crural artery, but not if these levels are mixed. Some modifications have been proposed (e.g., adding weighting coefficients), but these have not been validated *prospectively* as being better than the original scheme and complicate the scheme even more. For these reasons and its relatively greater complexity it is not yet widely used, but because no other better system has come along in the last decade and replaced it, it has been retained in these standards, with modification to accommodate differences in pedal artery patency and clarification for easier understanding and application. However, it is realized that its utility is limited by the quality and accuracy of data collected from arteriograms and the types of compar-

Table VI, A. Weighting of runoff arteries (total of three units)—site

Site of distal anastomosis (artery)	*Number of units assigned*		
	3	*2*	*1*
Common iliac		External iliac	Hypogastric
External iliac	Common femoral	SFA	Profunda femoris
Common femoral		SFA	Profunda femoris
Popliteal above-knee	Distal popliteal		Anterior tibial
Popliteal below-knee			Posterior tibial
			Peroneal
Anterior tibial		Distal tibial	Pedal arch
Posterior tibial		Distal tibial	Pedal arch
Peroneal		Pedal runoff	Collaterals to anterior and posterior tibial arteries
Pedal/inframalleolar			

SFA, Superficial femoral artery.

Table VI, B. Weighting of runoff arteries (total of three units)—occlusion

	Number of points assigned per unit				
Degree of occlusion	*3*	*2.5*	*2*	*1*	*0*
Major runoff vessels	Occluded throughout length	Occluded less than ½ of length; visible collaterals	50% to 99% greatest stenosis	20% to 49% greatest stenosis	Less than 20% greatest stenosis
Pedal runoff	No primary pedal artery patent	Partially patent or fully patent beyond critical in line occlusive lesion	In line continuity with patent outflow vessel but incomplete arch	One or more subcritical stenoses distally but no in line	Fully patent pedal runoff (<20% stenosis)

isons that it helps define (e.g., similar bypass grafts to similar outflow sites). Therefore, it is not recommended to the exclusion of other schemes.

As seen in Table VI, this scheme grades *both* the degree of occlusion *and* the relative contribution to outflow of each runoff vessel, from 0 to 3, then adds 1 to the product of these two grades, resulting in a decimal scoring system that assigns 1 to a widely patent runoff and 10 to an isolated, blind segment with no major vessel runoff. In this scheme, higher values correspond with higher resistances so that resistances in series and in parallel (as in axillobifemoral and sequential bypasses) can be graded. Calculations for some of the more complex examples of this scheme are illustrated in Figs. 3 and 4. Obviously, most calculations will be much simpler than these.

EXPLANATION:

1. Three "weighting units" are divided among the major runoff arteries in the segment below or beyond the terminal anastomosis, according to their normal relative contribution to runoff or outflow. The dominant of two runoff vessels is assigned two of the three units (e.g., superficial femoral = 2, profunda femoris = 1), whereas three more or less equal runoff vessels, like the three infrapopliteal arteries, are assigned one unit each (see Table VI and Fig. 3, *A*). A normally single vessel outflow (e.g., the popliteal artery in an above-knee femoropopliteal bypass graft) may receive all three weight units, or these units may be individually assigned to each of its runoff vessels (e.g., the tibial and peroneal arteries) ***depending on which is considered to present the greatest degree of occlusive disease and resistance to runoff*** (i.e., the highest calculated runoff score). Weighting units for each lower extremity artery are shown at the top of Table VI.

2. A "resistance value" is also assigned to *each* outflow artery, with a maximum resistance value of 3. As shown in the bottom half of Table IV, three "resistance" units are assigned to a vessel that is totally occluded throughout its length, two units to one with a 50% to 99% stenosis, one unit for a 20% to 49% stenosis, and none if widely patent.

3. A modified scheme is offered for pedal artery runoff. In pedal or paramalleolar bypass grafts or those to a single patent infrageniculate artery terminating in the pedal arch, the recipient artery or the pedal arch may be assigned all three weighting units, whichever offers the highest resistance. In grading the resistance of the pedal arch, zero is assigned for

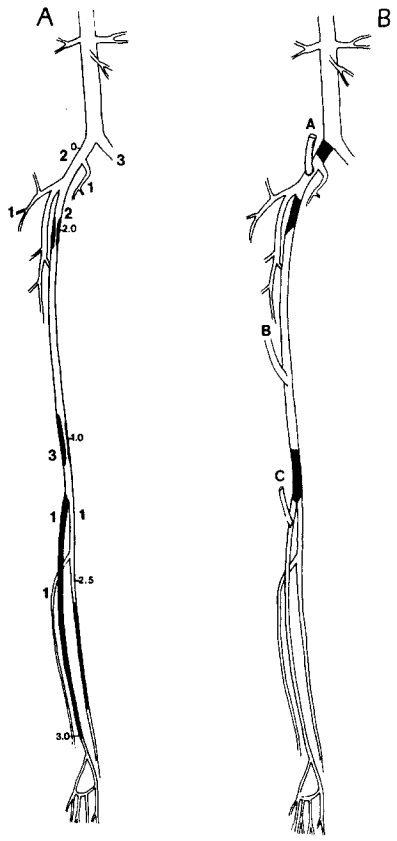

Fig. 3. A, *Bolder numbers* indicate value, out of possible total of 3, assigned to each vessel; numbers in *finer print* indicate values assigned to varying degrees of occlusion (Table IV). **B,** Runoff resistance values are calculated as follows for grafts that enter the three levels indicated: Level *A,* superficial femoral = 2 × 3; profunda femoris = 1 × 0; total = 6 + 0 + 1 = 7. Level *B,* distal popliteal blind segment = 3 × 3 + 1 = 10. Level *C,* anterior tibial = 2 × 0; arch = 1 × 0; total = 0 + 0 + 1 = 1.

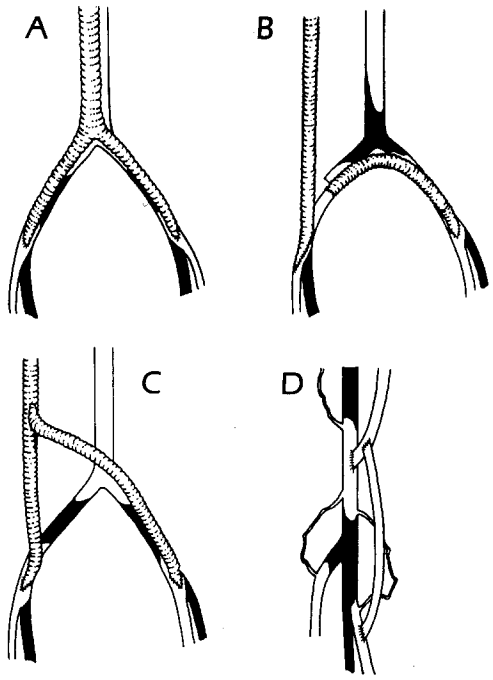

Fig. 4. In each of three graft configurations *(A to C),* individual runoff values for right and left limbs are 7 and 4, respectively. Values for aortobifemoral stem *(A),* entire right axillofemoral graft *(B),* and proximal axillofemoral stem *(C)* are all 2.5 (1/R = 1/4 + 1/7 = 11/28 = 1/2.5). However, distal axillofemoral limb *(C)* has runoff resistance value of 7. *D* shows a sequential bypass graft where resistance values of proximal and distal limbs are 10 and 1, respectively. Combined they give a resistance value for proximal stem of 0.9 (1/R = 10/10 + 1/10 = 11/10 = 1/0.9).

completely patent arch connecting with retrograde flow back into the other pedal artery (e.g., lateral plantar or medial tarsal), 1 for patent arch with no retrograde outflow, 2 for a diseased or partially occluded arch, and 3 for little or no arch visualized.

4. The sum of the products of the weighting unit multiplied by the resistance value for each major runoff artery is added to a base "resistance" of one, in recognition of the fact that even a widely patent distal bed offers some resistance. This creates a decimal runoff resistance score, in which a blind segment carries a value of 10 and a widely patent system is scored as 1. The contribution of each occlusive lesion to runoff resistance depends on its artery's relative weight. Thus a 60% stenosis of a posterior tibial artery below a below-knee femoropopliteal bypass graft would have a resistance value of (2 × 1) 2 points, the same stenosis in the superficial femoral artery below a femorofemoral bypass graft would be assigned (2 × 2) 4 points, whereas this degree of narrowing in the popliteal artery below a femoropopliteal above-knee bypass graft would contribute (2 × 3) 6 points to the runoff score.

5. In multiple outflow bypass grafts, as in the two limbs of aortobifemoral and axillobifemoral bypass grafts, the reciprocal sum of each outflow artery is added in grading resistance in the proximal limb or stem (i.e., 1/R stem = 1/R left limb + 1/R right limb), but each distal limb of the graft is graded alone for correlation with graft limb patency (see examples given in Fig. 4).

If a simplified four-level runoff grade is desired, the above system can be used in part to produce a 0 to 3 score. If two or more major vessels constitute the normal runoff, the "weighting units" above (see

explanation #1) can be applied in an all-or-none fashion, assigning those points when there is a hemodynamically significant occlusive lesion (e.g., >50% stenosis) in the vessel in question. For example, for bypass grafts that terminate in the common femoral artery, 2 out of a total of 3 points would be assigned if the superficial femoral artery was occluded. Because bypass grafts to the popliteal artery are usually affected by crural artery occlusive disease, this same approach can be used. Thus an occluded posterior tibial artery and a 60% stenosis of the anterior tibial origin would receive 2 out of 3 points, much like previous 1 to 4 grading schemes. Bypassing to a single tibial artery or the dorsalis pedis are examples of a normally single-vessel runoff. Because it is unlikely that this procedure would be performed to a vessel with a hemodynamically significant stenosis, runoff will normally be determined by the pedal arch, and the 0 to 3 score offered for this above (see explanation #3) can be applied. Arbitrarily, 1 point would be added to this score in bypass grafts to a peroneal artery, in recognition of its lack of direct connection with the pedal artery circulation. These simpler alternatives are offered as a compromise, for use when runoff grading is included in the analysis along with other risk factors mainly to characterize overall case severity in reported series. The full scheme is still recommended whenever runoff is a critical aspect of the outcome comparison.

CATEGORIZATION OF OPERATIONS AND PROCEDURES

Definitions. It is important to identify, if not separate, primary and secondary operative procedures, principal and adjunctive procedures, and types of procedures that differ characteristically in what they basically accomplish (e.g., reconstructive, restorative, nonreconstructive, and ablative). The following definitions are suggested and should be followed for uniform reporting. A "primary" operation or procedure is the first of *a given type* ever performed on a particular arterial segment. Subsequent operations, or other revascularization procedures of the same type, performed on the same arterial segment are designated "secondary." For example, if profundaplasty or balloon angioplasty of the superficial femoral artery fails to adequately relieve foot ischemia, and a femoropopliteal or femorotibial bypass procedure is subsequently performed, these later procedures may still be considered primary procedures because they are entirely different types of operations. However, if a femoropopliteal bypass procedure has been performed and it is redone or extended down to a tibial artery, these two later procedures would be called secondary operations. Such secondary procedures, even if performed as the *first* operation in a different institution or by a different surgeon in the same institution, are still considered secondary operations.

A "principal procedure" is the one that the surgeon believes to contribute the most to improving the arterial circulation. An "adjunctive procedure" is any other simultaneous or planned subsequent (i.e., staged) procedure that is designed to augment the effects of the principal procedure, such as arterial balloon dilation, sympathectomy, or profundaplasty performed with a femoropopliteal bypass procedure. An "ancillary procedure" is one that does *not* contribute to the overall hemodynamic effect, such as an intraoperative arteriogram, a sartorius muscle flap for coverage, or a "prophylactic" fasciotomy.

An "elective operation" is one that is performed without urgency and is scheduled during regular operating time at the mutual convenience of both the patient and the surgeon. An "urgent operation" is one that is intended to be performed as soon as the necessary preoperative preparation and diagnostic studies can be completed. An "emergency operation" is one that must be performed as soon as possible, often without time for adequate preoperative study or preparation, because of an immediate threat to limb or life.

A "reconstructive procedure" is an open procedure that is performed to remove, replace, or bypass an obstructive or aneurysmal lesion involving the vessel wall and restore pulsatile flow beyond the involved segment. This category would include bypass grafting, interposition grafting, resection and anastomosis, endarterectomy, or surgical angioplasty with patch graft.

A "restorative procedure" is one in which the obstructing element (often clot or plaque) is removed or displaced from the lumen of an arterial or venous segment, allowing flow through the lumen to be restored to normal or near normal without direct reconstruction. This is often done through a limited and even remote point of access, leaving the involved segment basically intact. Examples include thrombectomy, embolectomy, enzymatic thrombolysis, laser plaque destruction, atherectomy, and transluminal balloon dilation.

Both of the above types of interventions are grouped under "revascularization" procedures. In contrast, a "nonreconstructive procedure" is any procedure that is designed to improve or to protect

blood flow without using direct vascular reconstruction. Included would be sympathectomy, fasciotomy, and release of compression of the artery, as by division of a band or resection of a rib. "Ablative procedures" are those that are designed to remove nonviable or diseased material or that interrupt flow in patent vessels. These would include major or minor amputation, debridement, or removal of an infected graft. Ligation of an arterial segment is included here although nothing is removed.

Finally, when the original procedure deteriorates or fails and corrective measures are taken to restore or preserve functional patency, it is important to distinguish between revisions and "redo" procedures, even though both may be called secondary reconstructions. In a "revision," there is retention without significant modification of all or most of the graft or reconstructed segment, as in patch angioplasty. Distal extension from a graft that is or has been rendered patent throughout most of its length may also be considered a revision rather than a "redo." A "redo" implies replacement or bypass of all or most of the graft or reconstructed segment (e.g., does not retain at least the majority of the previous graft and one of its anastomoses).

Grouping and characterization of lower extremity revascularization procedures. In addition to the broad categories defined above, lower extremity vascularization procedures can be characterized by type of procedure (e.g., endarterectomy, interposition graft, bypass procedure, embolectomy, or balloon dilation), location with identification of the arterial segment operated on or the proximal and distal sites of a bypass graft or endarterectomy, and side (e.g., right, left to right, or bilateral). Additional specific details, such as graft type, shape, size, type of anastomosis, anatomic route of a bypass graft, and incisional approach, are worth documenting but may create so many variables that innumerable subgroups would be required and defy categorization. Therefore, there is a need for a more inclusive system of grouping, allowing similar procedures to be compared. The following general groupings are suggested for lower extremity revascularization procedures. This system divides procedures according to whether they are direct or indirect (extraanatomic or ex situ) and whether they deal with occlusive disease proximal to, at, or distal to the femoral bifurcation.

1. Direct (in situ) *proximal* revascularization: includes aortoiliac, iliofemoral, and aortofemoral endarterectomy or bypass procedures, unilateral or bilateral.
2. Indirect (ex situ) *proximal* revascularization: includes such extraanatomic bypass procedures as axillofemoral, crossover femorofemoral, axillobifemoral, and thoracoaortofemoral.
3. Direct (in situ) *femoral* revascularization: from external iliac to proximal superficial and profunda femoral arteries; includes profundaplasty by endarterectomy and/or patch angioplasty.
4. Indirect (ex situ) *femoral* revascularization: includes obturator bypass, axillopopliteal, and crossover femoropopliteal bypass procedures.
5. Distal revascularization: includes most infrainguinal bypass procedures, such as above-knee femoropopliteal bypass, below-knee femoropopliteal bypass, femorocrural and femoropedal bypasses, above-knee and below-knee popliteocrural and above-knee and below-knee popliteopedal bypass and sequential femorodistal bypasses to popliteal, crural, or pedal arteries. Differentiation between an in situ or ex situ graft course here does not warrant subcategorization (and may be confusing because an in situ vein bypass would actually be an ex situ or extraanatomic revascularization).

COMMENT: When comparing procedures that are "competitive" for revascularizing a particular arterial segment, as in comparing aortobifemoral and axillobifemoral bypass procedures or surveying the overall results of surgical management of aortoiliac occlusive disease, it is appropriate that such different procedures be included in one report. On the other hand, when comparing two or more technical or treatment variables, such as graft types or antithrombotic drugs, with graft occlusion as the end point, it is recommended that broad categories that contain multiple operations *not* be combined. Instead, these variables should be compared on the same or very similar procedures.

The category "femorofemoral bypass grafts" should include all similar crossover grafts whether the origin is the external iliac artery or the termination the profunda femoris artery. Similarly, femoropopliteal and femorocrural grafts should include those that also originate on the external iliac, superficial femoral, or profunda femoris arteries. However, the proportion of each different origin and termination can and often should be noted. In the important instance of above-knee compared with below-knee popliteal termination of a graft, separation into two groups is preferable to simply noting the proportion of each and then evaluating them together. Multiple added or sequential outflow distal bypass grafts are better considered separately and not included with

Table VII. Types of complications with suggested grading for outcome and severity

Complication (type)	*Severity/outcome**
Systemic/remote	
Cardiac	
Ectopic/arrhythmia	1 = little/no hemodynamic consequence
Congestive failure	2 = symptomatic/required treatment
Myocardial infarction	3 = cardiac arrest/fatal
Stroke/TIA	1 = TIA/temporary deficit
	2 = permanant deficit
	3 = fatal
Deep venous thrombosis	1 = hospitalization not prolonged
Suspected	2 = treatment prolonged hospitalization
Confirmed	3 = required operation
Pulmonary embolism	1 = mild, required antithrombotic drugs
Suspected	2 = serious, required resuscitation
Confirmed	3 = severe, required embolectomy or fatal
Coagulation complications (including drug-induced)	
Spontaneous hemorrhage	1 = resolving without treatment
Thrombocytopenia	2 = requiring drug therapy
"White clot syndrome"	3 = requiring operation or fatal
Thrombosis from ATIII, protein C or S deficiency	
Renal insufficiency	1 = transient, not requiring dialysis
Contrast media–induced	2 = transient, required dialysis
Thromboembolic	3 = permanent (dialysis, transplant, death)
Ischemic (acute tubular necrosis)	
Obstructive	
Local/vascular	
Graft infection	
Early (<30)/late (>30 days)	1 = successful local treatment
Culture positive/negative	2 = required graft removal/bypass
Noninvasive (exposed, contaminated)	3 = loss of limb/life
Invasive, involves graft or anastomoses	
Complications of graft/vessel interaction	
Intimal hyperplasia (arteriographic, intraoperative, or pathologic diagnosis	1 = observed, no treatment required 2 = local treatment sufficed (dilation/revision, local resection)
Proximal anastomosis	3 = required "redo" operation
Distal anastomosis	
Anastomotic pseudoaneurysm	1 = observed, no treatment required
Mechanical	2 = local treatment sufficed (dilation/revision, local resection)
Infectious	3 = required "redo" operation
Graft complications (exclusive of anastomotic changes)	
Dilation/aneurysm	1 = observed, no treatment
Stenosis, focal/diffuse	2 = local treatment sufficed (dilation/revision, local resection)
Elongation/kinking	3 = required "redo" operation
Intrinsic, structural defect†	
Arteriosclerotic change†	
Technical†	
Anastomotic hemorrhage	
External bleeding	1 = observed
Internal (hematoma)	2 = required aspiration, drainage
	3 = required anastomotic repair, revision

*0 = none; 1 = mild; 2 = moderate; 3 = severe.
†These features apply to all subgroups of graft complications exclusive of anastomotic changes.
‡See Criteria for Significant Change in Status, p. 522.

either femoropopliteal or femorocrural bypass grafts (some reports have included each limb in each of these two categories). Patency rates of these and other multiple-termination grafts (e.g., aortobifemoral, axillobifemoral, above-knee femoral-popliteal-tibial) should be calculated by considering each graft limb separately.

REPORTING DEATHS AND COMPLICATIONS

Postoperative deaths may be a result of physician errors (in diagnosis, technique, judgement, or management) or, in their absence, to the disease of the patient. Late deaths are usually attributed to either the underlying disease, delayed complications of sur-

Table VII. Cont'd

Complication (type)	*Severity/outcome**
Local/vascular cont'd.	
Graft thrombosis	
Early/late	1 = not corrected or corrected with restorative procedure
Cause found	2 = required revision or "redo"
Cause not found	3 = limb loss (unexpected tissue loss)
Unsatisfactory hemodynamic result (despite patency)	
Insufficient inflow	1 = > + 1 (but less than expected)‡
Insufficient outflow	2 = + 1‡
"Steal"	3 = < + 1‡
Graft-enteric reaction	
Anastomotic (fistula) vs. nonanastomotic (erosion)	1 = successfully treated without permanant sequelae
Primary infectious cause vs. no secondary infection	2 = permanant sequelae (e.g., limb loss, -ostomy)
	3 = fatal outcome
Unexpected tissue loss/amputation	1 = minor tissue w/o amputation
	2 = minor amputation
	3 = major amputation
Atherothromboembolism	1 = without tissue loss
	2 = with minor tissue loss/amputation
	3 = with major tissue loss/amputation
Colon ischemia	1 = not requiring operation
	2 = colon resection or colostomy
	3 = fatal
Spinal cord ischemia	1 = transient
	2 = minor permanent deficit
	3 = major permanent deficit
Local/nonvascular	
Noninfectious wound fluid accumulations	
Hematoma	1 = observed, resolved
Seroma	2 = aspirated
Lymphocele	3 = surgical drainage
Wound infections	
Superficial	1 = treated with antibiotic
Deep	2 = treated with drainage
Exposed/contaminated graft	3 = required graft removal or bypass
Lymphatic disruption	
Lymphedema	1 = no treatment required
Lymphocele	2 = aspiration, drainage
Lymph fistula	3 = exploration with closure of lymphatics
Ureteral injury	
Complete obstruction	1 = resolved spontaneously
Partial obstruction	2 = required drainage, diversion
Urinoma (closed leak)	3 = surgical correction or nephrectomy required
Urinary fistula	
Sexual dysfunction	
Affecting ejaculation (e.g., retrograde)	1 = mild or no effect on sexual activity
Affecting fertility	2 = reduces sexual activity
Affecting erection (potency)	3 = prevents or eliminates sexual activity
Complications of sympathectomy	
Disturbance in ejaculation/potency	
Neuralgia after sympathectomy	
No demonstrable therapeutic benefit	

gical management, or are considered "unrelated." Both early (less than 30 days) and late (more than 30 days) deaths that occur after lower extremity revascularization procedures should be reported to give a truer perspective, and the additional breakdown offered earlier for late deaths is recommended.

Complications of lower extremity procedures can be either specific or nonspecific, but the separation between the two is often indistinct. The nonspecific category includes such problems as atelectasis, dehiscence, and congestive heart failure as well as some that, although not specifically related to operative technique, are nevertheless indirectly related to the procedure or to the underlying disease it treats. Examples are myocardial infarction, stroke, deep venous thrombosis, and pulmonary embolism. Even such universal complications as wound infection and

hemorrhage may be relatable to specific aspects of the patient's disease. Bypass grafting in the face of a septic foot or open ulcer will increase the chance of wound and graft infection, and the use of heparin or other antithrombotic drugs will increase the chance of wound hemorrhage. Therefore, it is suggested that complications that are specific to the operation *or* the underlying disease be reported. They fall into local vascular, local nonvascular, and remote systemic categories. In the case of some reported complications, it may be appropriate to separate further those that occur early in the postoperative period from those that develop later, with 30 days after operation used as the arbitrary dividing point.

Many complications are difficult to grade in terms of severity other than to identify them as causing death, causing permanent disability, necessitating reoperation, prolonging hospital stay, or otherwise, as "insignificant." Table VII lists types of complications, with a breakdown into subtypes that might be valuable to consider in reports on lower extremity revascularization, as well as suggested grading for outcome or severity.

FINAL COMMENT

These standardized reporting practices are recommended primarily to allow clinical studies on various aspects of the management of lower limb ischemia to be read with confidence and compared with validity. They are still in evolution and, as this new version attests, will require periodic revision. It is further hoped that the grading schemes and outcome criteria featured here will be incorporated into clinical databases and provide a common foundation, in the form of disease severity scoring,[39] for valid outcome comparisons.

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