Skin perfusion pressure measurement is valuable in the diagnosis of critical limb ischemia

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Purpose: Critical limb ischemia (CLI) is equated with a need for limb salvage. Arterial reconstruction and major amputation are the therapies ultimately available to such patients. We studied whether measurements of skin perfusion pressure (SPP) can be used to accurately identify those patients with CLI who require vascular reconstruction or major amputation and distinguish them from patients whose foot ulcer would heal with local wound care or minor amputation.

Methods: Fifty-three patients with a total of 61 limbs with a nonhealing foot ulcer (age range, 47 to 88 years; mean, 70.8 ± 9.8 years; 33 men, 20 women) who were referred to the Vascular Laboratory at Morristown Memorial Hospital for evaluation of arterial insufficiency were studied in a prospective, double-blinded fashion. Patients were included in the study if informed consent was obtained, and patients were excluded if there was uncontrolled sepsis or if they required guillotine amputation. The size and site of the foot ulcer was recorded. If gangrene was present, the location and extent was also noted. The pulses were examined and recorded, and the ankle-brachial index was determined for each limb. Measurements of SPP were made at the proximal margin of the ulcer in viable tissue (not in the bed of the ulcer). SPP measurements were made independent of the vascular surgeon's evaluation of the limb and were not part of his clinical decision regarding management of the foot ulcer. The SPP measurements were compared (Fischer's exact test) with the clinical decision for therapy (group I, arterial reconstruction or major amputation; or group II, wound debridement, minor amputation, or both). SPP was also compared with the outcome (ulcer healed or failed to heal) of therapy in group II. From contingency tables we calculated the sensitivity, specificity, positive and negative predictive values (PPV, NPV), and the overall accuracy of SPP measurement as a diagnostic test for critical limb ischemia.

Results: There was no difference in the size or location of foot ulcers between groups I and II, nor was there a difference in ulcer size or location between limbs that healed and did not heal in group II. The prevalence of diabetes was similar in all groups and subgroups. The ABI was not predictive of the need for reconstruction or major amputation nor the outcome of local therapy. SPP measurements identified 31 of 32 limbs diagnosed as having CLI by clinical evaluation (i.e., group I, those limbs that required vascular reconstruction or major amputation). Of those patients who were clinically assessed as not having CLI (group II), SPP measurements diagnosed 12 of the 14 limbs that did not heal as having CLI (PPV, 75%) and 11 of 15 limbs that did heal as not having CLI (NPV, 85%). The sensitivity of SPP less than 30 mm Hg as a diagnostic test of CLI was 85%, and the specificity was 73%. The overall diagnostic accuracy of SPP less than 30 mm Hg as a diagnostic test of critical limb ischemia was 79.3% ($p < 0.002$, Fischer's exact test).

Conclusions: We conclude that SPP measurement is an objective, noninvasive method that can be used to diagnose critical limb ischemia with approximately 80% accuracy. (J Vasc Surg 1997;26:629-37.)

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A noninvasive test that accurately diagnoses critical limb ischemia (CLI) in both diabetic and nondiabetic limbs would greatly aid in the management of patients with arterial insufficiency. CLI is defined by either of the following criteria: (1) recurring ischemic rest pain requiring analgesic, with an ankle systolic pressure of 50 mm Hg or less or a toe pressure of 30 mm Hg or less; or (2) ulceration or gangrene of the foot or toes with similar hemodynamic parameters.[1,2] The fate of a limb with CLI is well known to vascular surgeons: arterial reconstruction to save the foot or amputation at a level consistent with wound healing. Currently available noninvasive vascular laboratory tests do not definitively diagnose CLI. The difficulty of defining CLI with a noninvasive test value has been recognized.[1,3,4]

We have shown that skin perfusion pressure (SPP) may provide an objective measurement of CLI by studying SPP and its relation to healing in amputation wounds.[5,6] The SPP measurement is noninvasive, but unlike other noninvasive physiologic tests that measure pressure in the limbs it is not affected by medial calcific sclerosis ("noncompressible" arteries), which can cause spurious elevations in the segmental systolic pressure measurements.

We tested the hypothesis that SPP measurement can correctly diagnose CLI by comparing the SPP value with the treatment outcome (healed/healing failure) in patients with lower extremity arterial insufficiency and foot ulceration who were selected for local wound therapy, minor amputation, or both. Based on our investigation of SPP in amputation wound healing, an SPP less than 30 mm Hg was deemed a positive result for CLI. An SPP of 30 mm Hg or greater was considered a negative result.

We reasoned that if patients were inappropriately assigned to conservative management, healing would not occur. Foot ulcers in critically ischemic limbs should fail to heal with local therapy (debridement, minor amputation, or both). We compared the outcome (healing or healing failure) with SPP to determine whether SPP or clinical judgement supported by standard noninvasive vascular tests was better in diagnosing CLI.

A diagnostic test that accurately selects patients who are in need of arterial reconstruction and predicts which ulcers will heal with conservative therapy can be said to diagnose CLI. Current noninvasive tests for the diagnosis of CLI are inadequate.[7,8] For example, segmental systolic pressures are falsely elevated by arterial wall calcification that makes the vessel incompressible. Obviously, segmental systolic pressures cannot be used in such patients to define a critical level of ischemia. Toe pressures cannot be measured in thickly callused toes, surgically absent toes lost to prior amputations, or toes with extensive ulceration or gangrene. SPP can be measured anywhere on the limb that viable tissue is present. If SPP is shown to be a good test of CLI, it would be preferable to other noninvasive tests because it is consistently applicable to all limbs that require evaluation for critical ischemia. In addition, such a test would standardize study populations and thus would help to clarify the evaluation of therapies in critically ischemic limbs. An accurate diagnostic test of CLI would reduce cost by eliminating long, often unsuccessful attempts at conservative management.

METHODS

From June 1, 1993, to November 30, 1995, 61 limbs with foot ulceration or gangrene were studied in 53 patients who had been referred to the Vascular Laboratory at Morristown Memorial Hospital for evaluation of arterial insufficiency. Patients were excluded if there was uncontrolled sepsis or they required guillotine amputation. On referral to the Vascular Laboratory for evaluation of arterial insufficiency with ankle-brachial systolic pressure index (ABI), informed consent was obtained for the SPP test.

There were 33 men and 20 women. Their age range was 47 to 88 years, with a mean age of 70.8 years. Three fourths of the patients had diabetes mellitus. The presence or absence of pulses at femoral, popliteal, posterior tibial, and dorsalis pedis arteries was recorded. The size and site of the foot lesion was also recorded.

Management of foot ulcers was based on clinical judgment and the results of standard noninvasive testing (ABI), but not on SPP. A vascular surgeon decided which limbs warranted arterial reconstruction or major amputation (group I) and which limbs could be managed by debridement, minor amputation, or both (group II). His decision was based on the condition of the limb and the values of segmental systolic pressures at the thigh, calf, and ankle.

To measure the SPP, we used a laser Doppler scanner (Vasamedics, St. Paul, Minn.) modified for this measurement.[6] Briefly, the laser Doppler skin perfusion pressure transducer consisted of the laser Doppler probe secured within the bladder of a blood pressure cuff, which contained a transparent polyvinylchloride window, so that the microcirculatory perfusion measurements could be made during cuff deflation. The dimension of the cuffs were: foot, 7 × 40 cm; toe, 3.5 × 1.8 cm. We have studied the reproducibility of SPP measurements using the laser

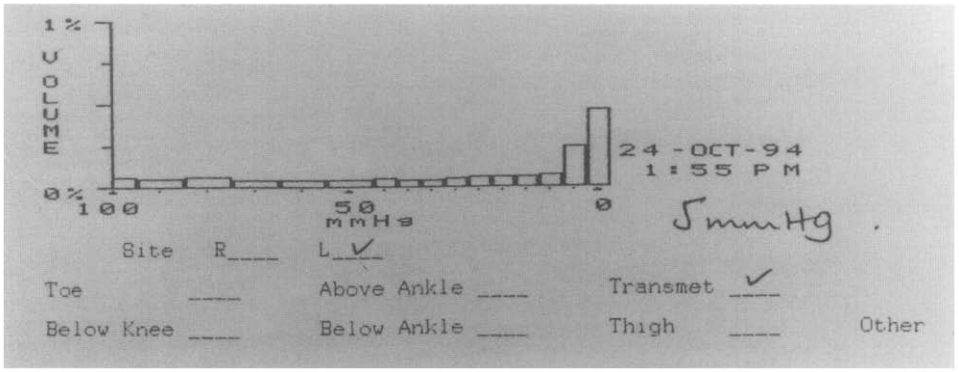

Fig. 1. Display of skin perfusion pressure monitor showing bar chart registering degree of skin perfusion for each pressure interval applied by blood pressure cuff encircling limb with critical ischemia and SPP of 5 mm Hg.

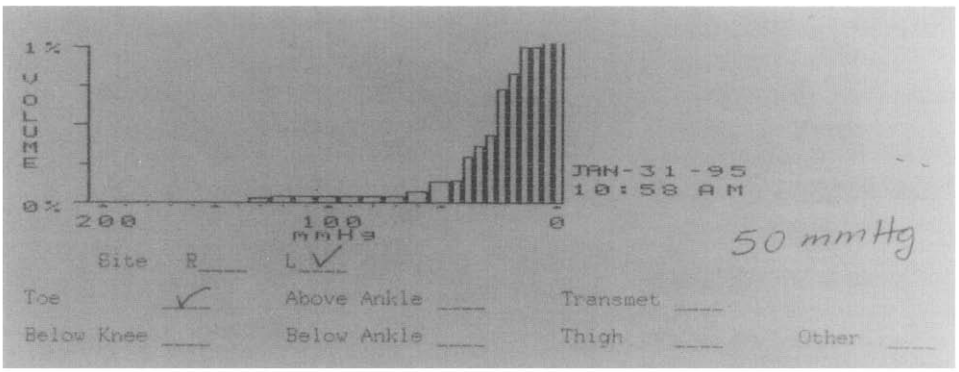

Fig. 2. Same display as in Fig. 1 for a limb without critical ischemia with an SPP of 50 mm Hg.

Doppler scanner and found it to be comparable with the reproducibility of brachial blood pressure measurements made with cuff and stethoscope.[9]

The sensor is attached to a special laser Doppler monitor, which also has a pressure port for connection to a pneumatic hose that supplies air to the bladder. The monitor is designed to register a bar chart that shows the degree of skin microcirculatory perfusion for each pressure (in volume percent units) interval (Figs. 1 and 2). After each patient was placed in a supine position, the SPP was measured at the proximal margin of the ulcer in viable tissue (not in the bed of the ulcer). Using a standard sphygmomanometer, the cuff was inflated to 5 mm Hg. This ensured a good contact between the laser Doppler perfusion pressure transducer and the skin. The skin perfusion value should be at least 0.3 volume % (laser Doppler flux) units. This value can be readily achieved even in severe ischemia and cold skin by applying a warm heating pad to the skin for 15 minutes. When perfusion was less than 0.3 volume % a heating pad was applied, which elevated skin perfusion above this level. To perform the test, the cuff is inflated to 20 mm Hg above the patient's brachial systolic pressure, and a stable skin perfusion value near zero (<0.1 volume %) is obtained. The cuff is then deflated in 10 mm Hg stepwise decrements every 5 seconds to a pressure of 50 mm Hg. Deflation then proceeds in 5 mm Hg decrements every 15 seconds until laser Doppler output increases for two consecutive pressure values. The pressure at which this first occurs (reinitiation of microcirculatory skin flow) is considered to be the SPP.

Patients were managed in the hospital and at the Wound Care Center of Morristown Memorial Hospital after discharge until their foot ulcers were healed or further definitive therapy was required. The SPP measurements were repeated twice, and the lower value was taken as the SPP. SPP measurements were compared with the clinical decision regarding

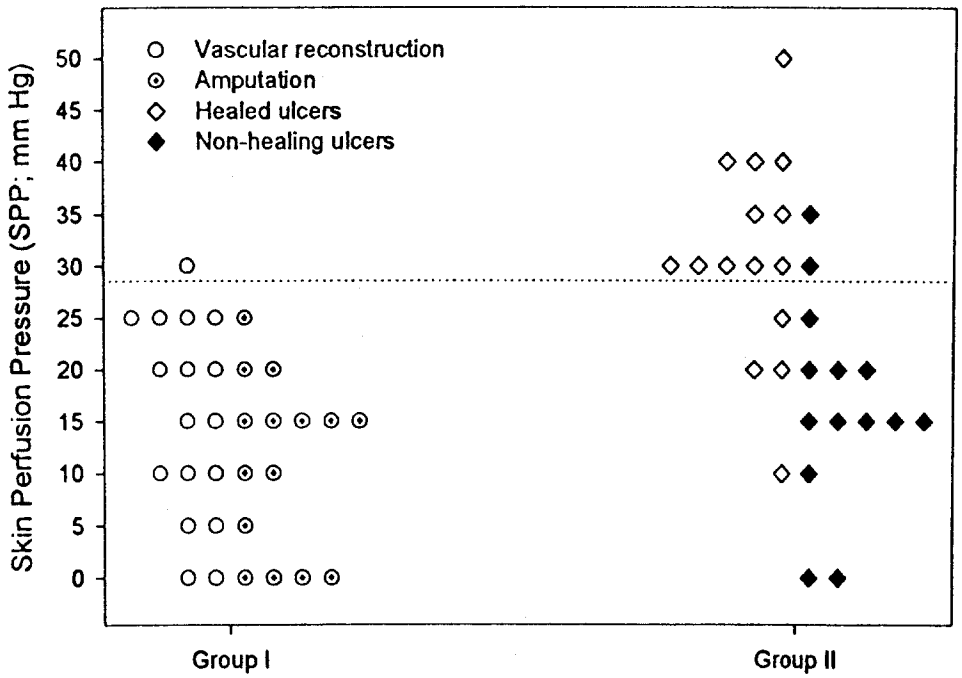

Fig. 3. SPP values for all limbs. Group I patients (n = 32) required vascular reconstruction or major amputation in the opinion of vascular attending surgeon. Group II patients (n = 29) were not thought to require vascular reconstruction to heal and were managed with local debridement, minor amputation, or both. All foot lesions and amputation wounds in group I healed.

management (placement in group I or II). Subsequently SPP and clinical judgment were compared with the outcome (healed/not healed) in patients placed in group II. From contingency tables, we calculated the sensitivity, specificity, positive and negative predictive values, and overall accuracy of SPP measurement. Logistic regression analysis was used to calculate the probability of foot ulcer healing for a given SPP value in group II patients.

Results were analyzed using a contingency table and Fischer's exact test. In addition, SPP values and outcomes were used to calculate a probability of healing for a given SPP value using logistic regression analysis. One-way analysis of variance was used to determine whether there was a significant difference in the size of foot ulcers or their location on the foot between group I and group II, and between group II healed and group II not healed.

RESULTS

Fig. 3 shows the SPP values for all limbs. Thirty-two limbs were identified by the vascular surgeon to require vascular reconstruction or major amputation (group I). Twenty-nine limbs were identified by the vascular surgeon as likely to heal without vascular reconstruction (group II). There was no difference in the prevalence of diabetes between group I and group II patients. There was no difference in the location of foot ulcers (heel vs forefoot) between group I and group II. There was no difference in the size of the foot ulcers between group I and group II (6.3 ± 5.1 cm^2 vs 6.7 ± 6.1 cm^2). Fig. 4 shows the SPP values for patients with and without diabetes in group II. The prevalence of diabetes (triangles) was similar in the healed and nonhealed limbs.

Only three patients were noted to have palpable pedal pulses, all of whom were in group II. The ABI for all limbs is shown in Fig. 5. The ABI could not be calculated in 17 limbs because of incompressible arteries (28%) of the limbs tested. There was no significant difference in the ABI between group I and group II nor in the mean ABI in group II patients whose foot ulcer healed and those whose ulcer did not (Fig. 6).

The SPP values of patients in group I were lower than 30 mm Hg in all but one patient selected for vascular reconstruction or major amputation (31 of 32). It is the outcome (healed/healing failure) of the

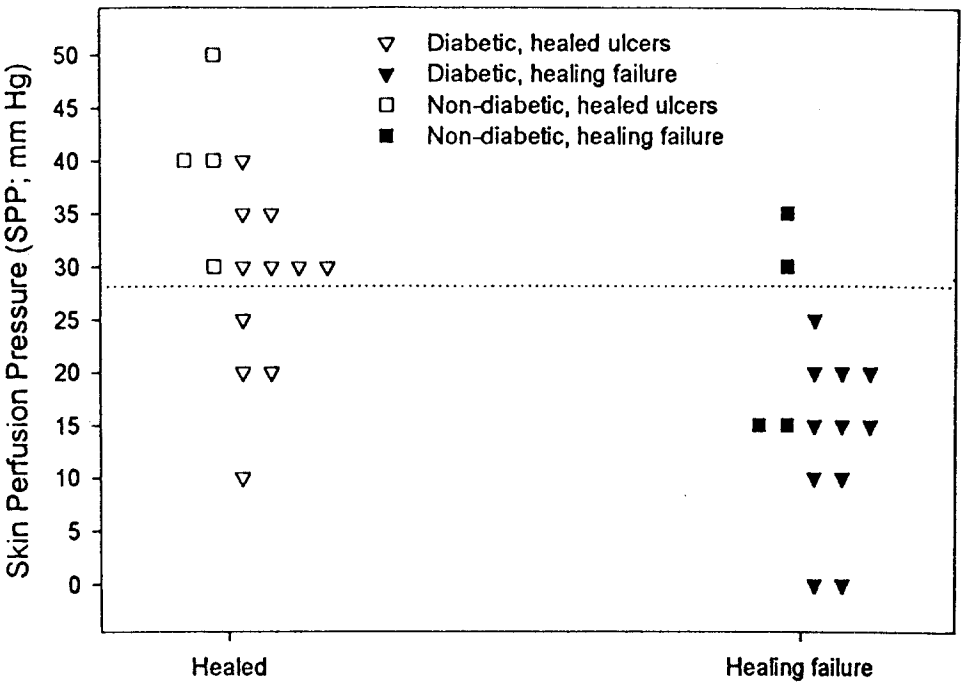

Fig. 4. SPP values for diabetic and nondiabetic patients in group II healed versus healing failure. There was no difference in the prevalence of diabetes in limbs that healed and limbs with healing failure.

patients in group II, rather than the fact that they were selected for group II, that is the better determinant of the accuracy of the SPP test for CLI.

Twenty-nine limbs were selected for local debridement or minor amputation in the belief that critical ischemia was not present. From the contingency table it can be seen that 15 limbs healed and 14 did not (Table I). There was no significant difference between the size of foot ulcers in the limbs of group II patients that healed compared with those that did not heal (6.7 ± 6.1 cm^2 vs 5.5 ± 3.6 cm^2).

Clinical judgment was accurate in choosing the appropriate therapy, and thus in the diagnosis of CLI, slightly more than half the time in this group II. A negative result of the SPP test ($\geq$30 mm Hg) for critical ischemia was found in 13 patients. The ulcers of eleven of these 13 patients healed. The predictive value of a negative test was 85%. The specificity of the SPP test was 73% in group II patients. The sensitivity was 85%. The overall diagnostic accuracy of SPP in diagnosing CLI was 79.3% ($p < 0.002$ Fischer's exact test) far better than clinical judgment.

Two patients with an SPP of 30 mm Hg or more did not heal. Both of these patients had atheroemboli indicating that a focal, rather than global, foot ischemia was responsible for failure of healing. Twelve of 16 limbs failed to heal when the SPP was less than 30 mm Hg. The positive predictive value of the SPP test was 75%. But the four patients who healed with SPPs less than 30 mm Hg did so beyond the 6-week limit traditionally used by vascular surgeons to define a nonhealing foot ulcer, indicating that borderline critical ischemia was probably present. ABI, when analyzed in a similar manner, had far too many false-negative tests to be useful either in the selection of therapy or the prediction of healing (Fig. 6).

Even with sufficient circulation to allow healing, other factors that affect healing may prevent a test that accurately excludes CLI from being a good predictor of healing, for example, when infection, pressure necrosis, peripheral neuropathy, foreign body, or metabolic or pharmacologic derangements are present. Fig. 7 displays our results using logistic regression to calculate the probability of healing for a given SPP value in patients in group II. This calculation may be a more practical way to present the results of the present study with respect to the prediction of ulcer healing, which is a related but different problem than the diagnosis of CLI. Fig. 7 shows that SPP values between 20 and 30 mm Hg do not predict healing with great accuracy. But an SPP value less than 20 mm Hg and an SPP value greater than

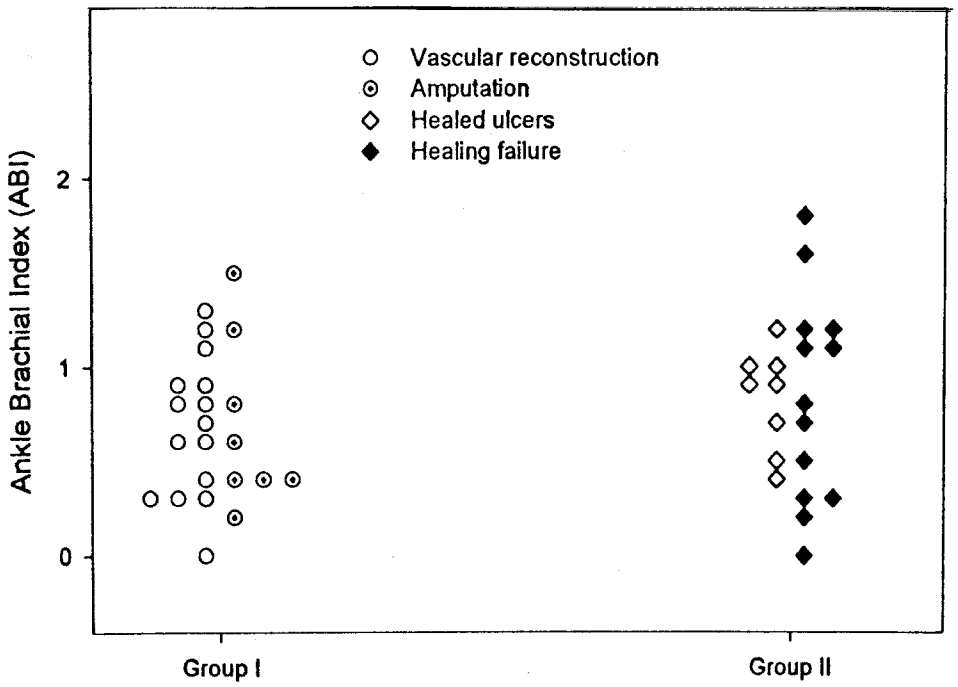

Fig. 5. ABI values for all limbs. There was no significant difference in mean ABI between group I and group II.

30 mm Hg predict the outcome of local therapy quite accurately.

DISCUSSION

These results show that SPP can accurately diagnose CLI. The SPP test should be considered as a criteria for the objective definition of CLI by such bodies as the European Consensus Conference on Critical Limb Ischemia. Why should SPP be effective where standard noninvasive tests have been less useful to the surgeon when selecting appropriate therapy for limbs with chronic ischemia?

The utility of Doppler ultrasound segmental pressure measurements has been confounded by medial calcific sclerosis present in a significant number of patients who have critical and subcritical limb ischemia. SPP is not affected by calcification of the media and thus allows the information contained in pressure measurements to be used in the assessment of every limb with compromised blood flow. Skin perfusion pressure and its relation to amputation, wound healing, and foot ulceration has been studied previously. The original work by Holstein suggested that values of SPP between 20 and 30 mm Hg were borderline but that pressures above 30 mm Hg indicated good healing potential, whereas pressures of 20 mm Hg and below were highly predictive of healing failure.[10]

Holstein and his colleagues[11,12] repeated their findings in a number of studies. A decade later, Dwars et al.[13] confirmed Holstein's findings in a well-designed prospective trial of the predictive value of skin perfusion pressure for amputation wound healing. Faris and Duncan[14] demonstrated the value of SPP in the prediction of healing of foot ulcers in diabetic patients, and Chelboun et al.[15] have recently confirmed the utility of SPP in this diagnosis, also correlating it with serum platelet-derived growth factor levels. Often these studies included side-by-side comparisons of other measures of limb ischemia, and just as often these other tests were found to lack predictive value, with the notable exception of toe pressures.

Patients with diabetes and occlusive vascular disease are difficult to evaluate accurately with noninvasive methods.[16] Segmental systolic pressures in such patients are unreliable because of medial arterial calcifications. More accurate evaluation is obtained with toe pressure measurements. Holstein et al.[12] found that toe pressure as well as SPP predicted healing of foot ulcers. Toe pressures, however, are often impossible to measure in this population, either because of the direct involvement of the digit in the gangrenous process, thick callus, or the absence of the toe because of previous minor amputation. We also occasionally

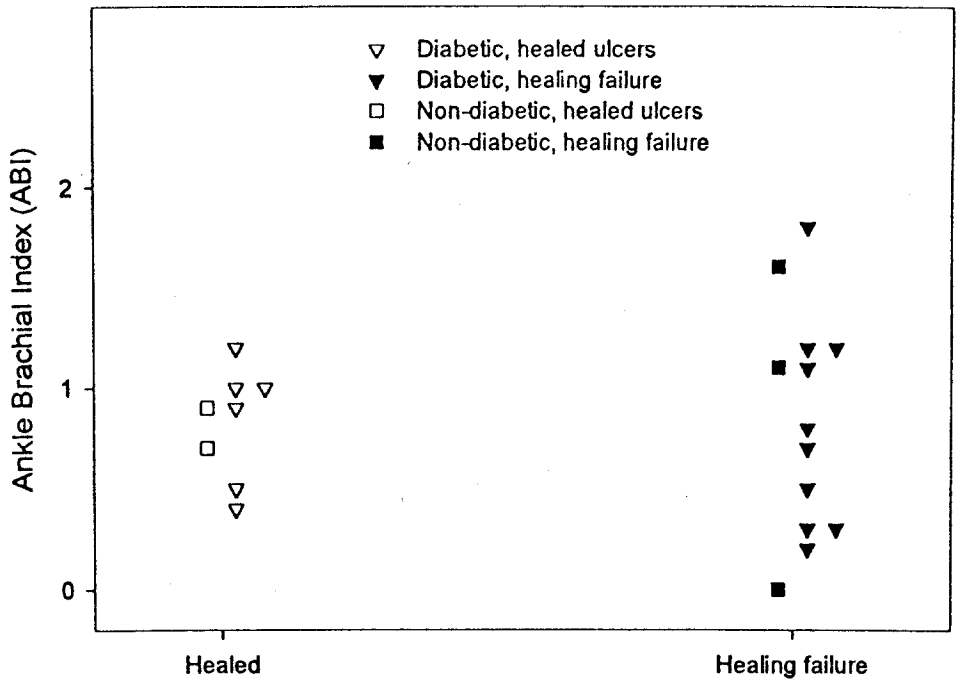

Fig. 6. ABI values for group II patients. There was no significant difference in mean ABI between healed and healing failure patients or between patients with and without diabetes, although the number of nondiabetic patients is probably too small in group II to draw a meaningful conclusion.

see incompressible digital arteries in the toe from medial calcinosis.

Another factor that may contribute to the diagnostic accuracy of SPP in the diagnosis of CLI is the fact that the measurement can be performed at the level of the limb or foot where the ulcer or amputation wound is located. The perfusion of the foot in the region of ulceration has to be extrapolated from a toe pressure. SPP can be measured at the region of interest.

An advantage of the laser Doppler method we described[17] over the radioisotope method used by Holstein et al., Faris and Duncan, and Dwars et al. is that it can be quickly repeated several times and the results verified, thus reducing the error of measurement. One caution is that in the radioisotope SPP method, histamine is injected in the skin to give a hyperemia. When ischemia is severe or when the foot is cold, skin blood flow may be too low to properly measure SPP (see Methods section). When skin perfusion is low (<0.3 vol. %), we briefly warm the foot with a heating pad so that the pressure at which perfusion returns to the skin (the SPP) can be readily identified.

The portability of the device described in this study makes bedside determination of SPP possible,

Table I. Comparison of healing outcome with SPP in patients managed with local debridement, minor amputation, or both (group II)

	Healted	*Nonhealed*	
Negative test SPP ≥ 30 mm Hg	11 [TN]	2 [FN]	NPV 85%
Positive test SPP < 30 mm Hg	4 [FP]	12 [TP]	PPV 75%
	Specificity 73%	Sensitivity 85%	

and this fact may increase the acceptance of SPP testing. Clearly, the radioisotopic method is cumbersome, expensive, and quite lengthy (>45 minutes). In comparison, the laser Doppler method is an entirely noninvasive technique with which an SPP determination can be made in less than 5 minutes.

Transcutaneous partial pressure of oxygen ($TCpO_2$) measurements have been suggested for the prediction of wound healing after amputation and in determining the correct management of diabetic foot ulcers.[18] The $TCpO_2$ test is relatively time-consuming (30 minutes to 1 hour), and the accuracy of $TCpO_2$ measurements in ischemic limbs has been

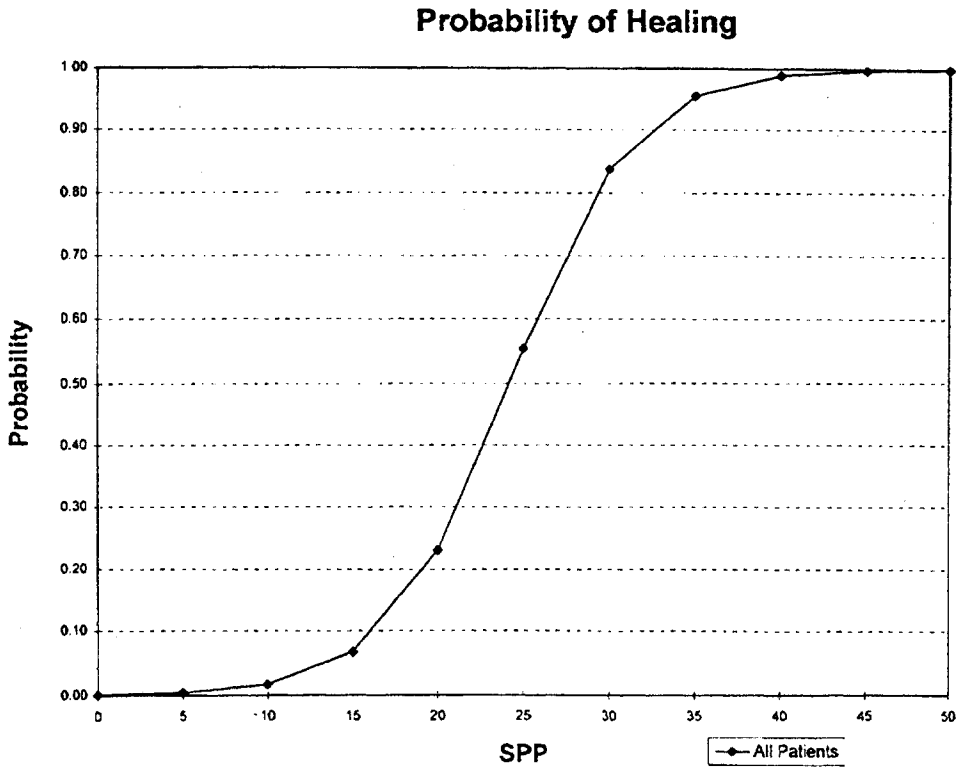

Fig. 7. Logistic regression analysis of patients in group II correlating a given SPP with probability of healing.

questioned. SPP should be studied in comparison with toe pressures and $TCpO_2$, and a trial that compares toe pressures and SPP in the evaluation of foot ulcers is needed.

We have taken wound healing to be the defining biologic process in CLI. If it cannot occur, critical ischemia is deemed to be present. Unfortunately, this retrospective definition cannot be applied prospectively in the course of clinical management. Nonischemic causes of nonhealing foot ulcers are presumed to have been excluded, but obviously neoplasia, chronic steroid therapy, the presence of a foreign body, and chronic trauma in a neuropathic foot are all causes of healing failure in limbs that are not critically ischemic. The commonly accepted definition of chronic CLI, namely a foot in which wound repair cannot take place, cannot be applied prospectively in the management of limbs with tissue loss.

There is presently no single diagnostic description or test that can be used in the prospective evaluation of patients with a degree of ischemia in whom healing is slow to occur. We believe that the results of the present study can be generalized to address the diagnostic definition of CLI. The definition of CLI has been the subject of a consensus document.[2] Fontaine class III and IV patients (those with rest pain, ulcer, or gangrene) and ankle pressure less than or equal to 50 mm Hg or a toe pressure less than or equal to 30 mm Hg were suggested by a multidisciplinary group as a definition to be used in clinical practice. But the document recognizes that patients with diabetic foot ulceration may have quite good circulation. As vascular surgeons are well aware, patients with diabetes, peripheral neuropathy, ulceration, and atherosclerotic occlusion of leg arteries with medial calcinosis may not fit neatly into the categories used in the consensus document. Seventy-five percent of the patients in the present study had diabete. There was no difference in the prevalence of diabetes in the clinical decision or clinical outcome groups in this study. Also, there was no statistical difference in the logistic regression curve relating the probability of healing to SPP in diabetic and nondiabetic patients (Fig. 7).

A number of recent articles and editorials recognize the difficulty in using the criteria of CLI contained in the consensus document in clinical decisions. It has been suggested that CLI must be redefined[8] and that assessment of the microcirculation may provide additional information in CLI.[4,19]

The present study suggests a role for SPP as an

objective measurement used in the definition of CLI and thus in the identification of ischemic foot ulcers unlikely to heal.

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