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Role of ankle peak systolic velocity in predicting healing of diabetic foot lesions in patients with critical lower limb ischemia

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Abstract

Aim

We designed the study for determining if ankle peak systolic velocity (APSV) has value in prediction of healing in diabetic foot lesions in patients with critical lower limb ischemia. APSV is the mean of the peak systolic velocities estimated at the ankle level over the distal tibial arteries.

Patient and Methods

Patients were included if they had diabetes foot lesions. Such lesions were ulcers, gangrene, or tissue necrosis. In addition, they had nonpalpable pedal pulses. Endpoints were healed or healing foot lesions, revascularization, major amputation, or death. Fifty diabetic limbs were included.

Results

Twenty-five (50%) limbs with diabetic foot lesions reached the end of adequate healing or complete healing following revascularization (all had endovascular intervention). Twenty-one (42%) limbs had failed revascularization and had been amputated, and four (8%) patients died. After revascularization, the median APSV of the 25 limbs with healed or adequately healing lesions was significantly higher than that of the 21 limbs with nonhealing lesions: 59.6 cm/s (30–90) versus 24.8 cm/s (10–60), $P < 0.0001$. At 37.5 cm/s as a cutoff value, it was found that the APSV showed a sensitivity of 90.5% (95% confidence interval: 84.3–98.1%), a specificity of 94.2% (95% confidence interval: 77.3–96%), a positive predictive value of 90.5%, and a negative predictive value of 94.2% in predicting nonhealing lesions of diabetic foot.

Keywords: Ankle, diabetic patient, peak systolic velocity

INTRODUCTION

The degree of peripheral ischemia is assessed commonly by the ankle-brachial index (ABI) [1]. Nevertheless, with the occurrence of arterial wall calcification, ABI is not accurate, as its results of being false are high. There is an alternative to this approach: the toe-brachial index (TBI) [2,3]. However, diabetic patients have a remarkable higher incidence of calcification of digital artery. Moreover, in some situation, as the toes are affected by ulcers or gangrene or have been amputated, we cannot measure toe pressures in those patients presenting with diabetic foot lesions. Therefore, TBI is invalid for assessment [4,5].

Now, we are discussing an alternative parameter for predicting the healing of diabetic foot lesions – the ankle peak systolic velocity (APSV) – because in ischemic limbs, blood moves

in the distal leg arteries at speeds lower in comparison within nonischemic limbs. This is observed angiographically and on duplex ultrasonography studies.

PATIENTS AND METHODS

This is a prospective study that included diabetic patients who presented to vascular surgery clinics at Ain Shams University Hospital and Mataria Teaching Hospital with critical limb ischemia in the form of tissue necrosis, ulcer, or gangrene, and with absent pedal pulses.

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The study included 50 consecutive limbs.

All patients were subjected to the following:

- (1) Full clinical detailed history
- (2) Full clinical examination, including the existence of foot lesions (ulcer or gangrene) and the presence of dorsalis pedis and posterior tibial pulses
- (3) ABI measurement of the affected limb
- (4) Duplex-detected APSV measurement of the affected limb.

The study included patients who presented with nonhealing lesions or manifestations such as tissue necrosis, ischemic ulcers, and ischemic gangrene (critical limb ischemia). These patients underwent the approach of revascularization by endovascular or open surgical technique.

A standardized protocol for daily dressings was followed for revascularized limb lesions, with a monthly follow-up. Follow-up was maintained until they reached one of the endpoints of the study, which are a healed wound, a healing wound, a nonhealing wound, or death.

A healed wound was considered if intact skin entirely covered the wound. Healing wound was considered if healthy granulations completely covered the wound with the absence of tissue necrosis or infection. Nonhealing wound was supposed to exist if no signs of healthy granulations had showed up after 1 month of follow-up, or if amputation was needed below and above the knee, or if critical limb ischemia manifestations developed.

An experienced operator performed duplex scanning with the room temperature adjusted to 22°C. A linear transducer of 5–12 MHz was used for the infrainguinal arteries with Doppler angle of insonation of 60°. With rest of 1 h before scanning, they were examined in the supine position. Recordings of the peak systolic velocities of the distal posterior tibial artery at or below the malleolar level and the distal anterior tibial artery just above the ankle joint level was done, and the average peak systolic velocities within three cardiac cycles were recorded.

No alterations were made to the patient's medications before scanning. If we found a focal stenotic lesion in one of the distal tibial arteries, we measured velocity distal to the stenosis. Data were prospectively maintained to be analyzed.

RESULTS

Baseline characteristics of the patients

A total of 50 limbs were included, belonging to 50 diabetic patients. The median age was 58 years (range: 44–82 years) (Table 1).

Clinical presentation before revascularization

The clinical presentation before revascularization of the included 50 limbs, belonging to 50 patients, in the study was as follows: 31 (62%) patients had foot gangrene, and 19 (38%) patients had foot ulcers (Table 2).

Type of lesions

The findings in the initial diagnostic test; digital subtraction angiography; multidetector-row computed tomography

angiography (MDCTA) were classified into four anatomic areas according to the level of the lesions: aortoiliac, femoropopliteal, infrapopliteal, and multilevel. Two (4%) patients in MDCTA group had lesions at the aortoiliac level, and five (10%) patients had lesions at the femoropopliteal level, six (12%) patients had infrapopliteal lesions and 37 (74%) patients had lesions at more than one level (multilevel) (Table 3).

Type of revascularization

In agreement with the vascular team, the vascular decision regarding the type of revascularization was as follows: two (4%) patients underwent surgical revascularization and 48 (96%) patients experienced endovascular revascularization (Table 4).

Table 1: Baseline clinical characteristics of the patients

	<i>n</i> (%)
Sex	
Male	23 (46)
Female	27 (54)
Age	
Mean±SD	58.6±8.2
Minimum	44
Maximum	82
Ischemic heart disease	
Negative	27 (54)
Positive	23 (46)
End-stage renal disease	
Negative	49 (98)
Positive	1 (2)
Hypertension	
Negative	20 (40)
Positive	30 (60)
Diabetes mellitus	
Negative	0 (0)
Positive	50 (100)
Smoking	
Negative	33 (66)
Positive	17 (34)

Table 2: Clinical presentation before revascularization

	<i>n</i> (%)
Clinical presentation	
Gangrene	31 (62)
Ulcer	19 (38)

Table 3: Type of lesions

	<i>n</i> (%)
Lesion type	
Aortoiliac	2 (4)
Femoropopliteal	5 (10)
Infrapopliteal	6 (12)
Multilevel	37 (74)

Results after revascularization

Following revascularization, 25 (50%) limbs had adequate healing or complete healing (all had endovascular intervention). Three (6%) limbs had nonhealing wounds (both had endovascular intervention). Six (12%) limbs had below-knee amputations following failed endovascular interventions, 12 (24%) limbs had above-knee amputation following failed revascularization (two bypass surgeries and 10 endovascular interventions), and four (8%) patients died (Tables 5 and 6).

Ankle-brachial index and healing

After revascularization, healed or adequately healing lesions was seen in 25 limbs. Their median ABI was significantly more than that of the 21 limbs with nonhealing lesions: 0.7 (0.6–1) versus 0.5 (0.2–0.9), $P < 0.001$ (Tables 7 and 8).

The relation between ankle peak systolic velocity and healing

After revascularization, the healed or adequately healing lesions were seen in 25 limbs. Their median APSV was significantly higher than that of the 21 limbs with nonhealing lesions: 59.6 cm/s (30–90) versus 24.8 cm/s (10–60), $P < 0.001$ (Tables 9 and 10).

Logistic regression analysis was performed to identify independent predictors of the nonhealing wound. All variables in this study except the APSV were shown to have a predictive value in healing versus nonhealing lesions.

We used the receiver operating characteristic curve to determine the cutoff value of APSV with the maximum sensitivity and specificity (Fig. 1). At a cutoff value of 37.5 cm/s, the APSV was found to show a sensitivity of 90.5% (95% confidence interval: 84.3–98.1%), a specificity of 94.2% (95% confidence interval: 77.3–96%), a positive predictive value of 90.5%, and a negative predictive value of 94.2% in predicting nonhealing of diabetic foot lesions.

DISCUSSION

Noninvasive vascular testing and vascular imaging such as digital subtraction angiography, Duplex ultrasound, MDCTA,

and magnetic resonance angiography are expanding in versatility and importance in diagnosing vascular disease. Today’s vascular surgeon needs expertise not only in interpreting them but also in personally performing some of them (e.g. noninvasive vascular tests, duplex scanning, and angiography) (Rutherford, 2005).

In diabetic patients, many methods of noninvasive prediction of wound healing or nonhealing of foot lesions have been described, for example, ankle-brachial pressure, toe-brachial pressure, transcutaneous oxygen, skin perfusion pressure, radioisotope clearance, photoplethysmography, and laser Doppler ultrasonography (Adera *et al.*, 1995).

The measurement of the ankle-brachial pressure is limited by that many diabetic patients had relative arterial wall

Table 4: Type of revascularization

	n (%)
Revascularization type	
Angioplasty	48 (96)
Surgical bypass	2 (4)

Table 5: Clinical data after revascularization

	n (%)
Clinical presentation after revascularization	
Healing	25 (50)
Above knee amputation	12 (24)
Below knee amputation	6 (12)
Death	4 (8)
Nonhealing	3 (6)

Table 6: Frequency of healing among studied patients

	n (%)
Healing	
Healing wounds	25 (50)
Nonhealing wounds	21 (42)

Table 7: Ankle-brachial index and healing

	Mean	SD	Minimum	Maximum
Ankle-brachial index after revascularization				
Nonhealing wounds	0.5	0.2	0.2	0.90
Healing wounds	0.7	0.2	0.6	1.00

Table 8: Relation between ankle-brachial index and healing using paired t-test

	Healing	Mean	SD	t	P	Significance
ABI	Healing wounds	0.7	0.2	3.633	0.001	HS
	Nonhealing wounds	0.5	0.2			

ABI, ankle-brachial index; HS, highly significant.

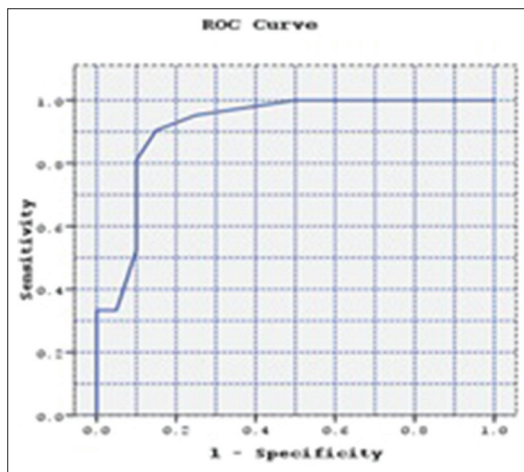


Figure 1: Receiver operating characteristic curve showing ankle peak systolic velocity (APSV) cutoff value at which healing and nonhealing occurs.

Table 9. Relation between ankle peak systolic velocity and wound healing using *t*-test

	Mean APSV	SD	Minimum	Maximum	<i>t</i>	<i>P</i>	Significance
APSV in healing wounds	59.6	17.1	30	90	6.067	0.000	HS
APSV in nonhealing wounds	24.8	16.3	10	60			

APSV, ankle peak systolic velocity; HS, highly significant.

Table 10. Comparative study between ankle-brachial index and ankle peak systolic velocity after intervention in healing and nonhealing wounds using paired *t*-test

	Mean	SD	<i>t</i>	<i>P</i>	Significance
ABI					
Nonhealing wounds	0.5	0.2	3.633	0.001	HS
Healing wounds	0.7	0.2			
APSV					
Nonhealing wounds	24.8	16.3	6.067	0.000	HS
Healing wounds	59.6	17.1			

ABI, ankle-brachial index; APSV, ankle peak systolic velocity; HS, highly significant.

calcification, which may make ankle pressure measurements not applicable to measure or falsely elevated [6].

In addition, the measurement of toe pressure is limited especially in the diabetic patients by calcification of the digital arteries and by the ulceration or tissue necrosis of the toes, which may make measurements of toe pressure inaccurate. APSV is not limited by these conditions (Quigley *et al.*, 1995) [7].

A cutoff value of 40 mmHg of skin perfusion pressure has a predictive value in wound healing with a sensitivity of 72% and a specificity of 88% (Yamada *et al.*, 2008) [8].

With a cutoff value of 34 mmHg of transcutaneous oxygen, measurements have a predictive value in wound healing with a sensitivity of 78.6% and a specificity of 83% (Faglia *et al.*, 2007) [9].

In our study, APSV had sensitivity and specificity comparable with previously reported results of skin perfusion pressure and transcutaneous oxygen.

The purpose of APSV is to measure the perfusion degree of the foot through blood velocity measurement in the distal anterior tibial artery and the distal posterior tibial artery at the ankle level supplying the foot.

APSV has a strong correlation with reliably measured ABI and TBI. Moreover, the Rutherford clinical classification of peripheral ischemia is well correlated with APSV. APSV is advantageous in some situation like in the presence of toe gangrene, amputation or vessel calcification.

In most centers for the assessment of peripheral ischemia, routinely arterial duplex scanning of the lower extremities, APSV is measured which takes no extra time and adds no additional cost.

In this study, APSV was used for the prediction of healing in diabetic foot lesions. If a low APSV exist, indicating

foot perfusion is significantly impaired, healing is hopeful. However, if a high APSV exists, indicating foot perfusion is adequate, wound healing may be reduced because of other factors. Therefore, using the parameter of APSV could be more appropriate for the prediction of nonhealing rather than healing.

In patients with diabetes, diseased or occluded anterior and posterior tibial arteries are often seen; the main blood supply to the foot is the peroneal artery with its two terminal branches. These are usually patent, even if the diseased or occluded two tibial arteries are found.

The foot perfusion supplied through the peroneal artery is efficiently reflected by calculating APSV with measuring the peak systolic velocity in the most distal segments of the anterior and posterior tibial arteries, which take their supply from the two peroneal artery's terminal branches (Taha *et al.*, 2004) [10].

Hoffmann and colleagues found in a 20-year literature review the assessment of complete ulcer healing as an endpoint. This endpoint was reported in only 0.9% of 1914 studies involving critical limb ischemia (Hoffmann *et al.*, 2007) [11]. They questioned if it was appropriate for using complete ulcer healing as an endpoint. In our study, we settled an endpoint as adequate healing. In agreement with almost reported studies on wound healing in patients with diabetes.

We used receiver operating characteristic curve to determine the cutoff value of APSV, with the maximum sensitivity and specificity, and found that a cutoff value of 37.5 cm/s was valuable as a prediction tool of nonhealing in this study. The cutoff value in nondiabetic patients may be lower.

CONCLUSION

The ABI, which is inaccurate especially in the presence of arterial calcification, is widely used for the assessment of the degree of peripheral ischemia. As digital arteries are less affected by calcification, an alternative, the TBI, has been used. TBI may be invalid in some situation as the toes are affected by ulcers or gangrene or have been amputated, and the incidence of digital artery calcification among people with diabetes is still significant.

Now, we are recommending an alternative parameter for predicting the healing of diabetic foot lesions: the APSV. We showed a cutoff value with high specificity and sensitivity in diabetic patients. Further studies are required to correlate this cutoff value with nondiabetic patients. Further studies with a large number of patients are suggested.

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Conflicts of interest

There are no conflicts of interest.

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