Comparative study of the Ankle-Brachial Index in diabetic and non-diabetic patients with critical limb ischemia

Estudo comparativo do Índice Tornozelo-Braquial em diabéticos e não diabéticos com isquemia crítica

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Abstract

Background: Calcification of the arterial tunica media can falsely elevate the Ankle-Brachial Index (ABI) in diabetics, making it difficult to assess arterial disease. **Objective:** To compare ABI values in diabetics and non-diabetics with critical ischemia. **Methods:** A total of 140 patients (60% diabetics) with critical ischemia due to infrainguinal peripheral arterial obstructive disease were recruited from the vascular surgery service at the Complexo Hospitalar Universitário Professor Edgard Santos. Mean ABI values for the two groups of patients were compared and correlated with severity of ischemia, according to the Rutherford Classification. Statistical analysis was conducted using EPI-INFO. **Results:** A majority of the 140 patients (77%) were classified as Rutherford Category 5, 6% as Category 4 and 17% as Category 6. Nine diabetics (11%) and one non-diabetic (2%) exhibited ABI > 1.15 ($p = 0.02$) and were excluded from the comparative analysis of mean ABIs. For the 130-patient sample, the 75 diabetic patients had a mean ABI for the posterior tibial artery of 0.26, vs. 0.28 for the 55 non-diabetic patients ($p = 0.6$); while mean ABIs for the dorsalis pedis artery were 0.32 vs. 0.23 respectively ($p = 0.06$). When the patients were stratified by Rutherford categories, there were no differences in mean ABIs in categories 4 or 5. Only mean ABI for the dorsalis pedis artery in Category 6 patients was significantly higher among diabetics (0.44 vs. 0.16; $p = 0.03$). **Conclusions:** The diabetic patients had a higher prevalence of falsely elevated ABI, but when these cases were excluded, mean ABI values were similar to those of non-diabetic patients, with the exception of ABI measured at the dorsalis pedis artery in patients with category 6 ischemia.

Keywords: diabetes mellitus; atherosclerosis; ischemia; Ankle-Brachial Index; complications of diabetes.

Resumo

Contexto: A calcificação da camada média arterial pode tornar o Índice Tornozelo-Braquial (ITB) falsamente elevado em diabéticos, dificultando a avaliação da doença arterial. **Objetivo:** Comparar os valores do ITB de diabéticos e não diabéticos com isquemia crítica. **Métodos:** Foram incluídos 140 pacientes (60% de diabéticos) acompanhados no Serviço de Cirurgia Vascular do Complexo Hospitalar Universitário Professor Edgard Santos com isquemia crítica por DAOP infra-inguinal. Comparou-se a média dos valores do ITB dos dois grupos de pacientes, correlacionando o ITB com a gravidade da isquemia, segundo a Classificação de Rutherford. A análise estatística foi realizada pelo EPI-INFO. **Resultados:** A maioria dos 140 pacientes (77%) se encontrava na Categoria 5 da Classificação de Rutherford, 6% na 4 e 17% na 6. Nove diabéticos (11%) e um não diabético (2%) apresentaram ITB > 1,15 ($p = 0{,}02$), sendo excluídos da análise das médias do ITB. Considerando os 130 pacientes, os 75 doentes diabéticos apresentaram média do ITB na artéria tibial posterior de 0,26 versus 0,28 dos 55 doentes não diabéticos ($p = 0{,}6$); e no ITB da artéria pediosa aqueles apresentaram média de 0,32 versus 0,23 desses ($p = 0{,}06$). Estratificando os doentes nas categorias da Classificação de Rutherford, não houve diferença nas médias do ITB nas categorias 4 e 5. Apenas em relação à artéria pediosa e em pacientes na Categoria 6, a média do ITB foi significativamente maior em diabéticos (0,44 versus 0,16; $p = 0{,}03$). **Conclusão:** Os diabéticos apresentaram maior prevalência de ITB falsamente elevado. Porém, excluindo-se esses casos, a média dos valores de ITB são semelhantes aos não diabéticos, exceto na artéria pediosa, nos pacientes com isquemia na categoria 6.

Palavras-chave: diabetes mellitus; aterosclerose; isquemia; Índice Tornozelo-Braquial; complicações do diabetes.

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INTRODUCTION

The Ankle-Brachial Index is a noninvasive method that is simple to evaluate and can provide important information for diagnosis, prognosis and follow-up of patients with peripheral arterial occlusive disease (PAOD).[1,2] In addition to the index's role in assessment of ischemic limbs, both ABI values below the limits of normality (≤ 0.9) and elevated values (over de 1.4) have been linked with mortality from cardiovascular disease.[1,3] Patients with critical limb ischemia (CLI), characterized by pain at rest and ulcers or gangrene secondary to PAOD, are at high risk of cardiovascular events such as myocardial infarction and stroke, in addition to the risk of limb loss.[1] Clinically, a diagnosis of critical ischemia can be confirmed by noninvasive examinations such as those needed to calculate the ABI and measurement of systolic pressure and transcutaneous oxygen tension.[1]

Calcification of the arterial tunica media or Monckeberg arteriosclerosis is more prevalent among diabetics and can interfere with compression of the arteries of the foot, leading to a falsely elevated ABI result.[4,5] Since calcification is more common at the level of the arteries of the foot, one alternative is to measure pressure in toes, which is thought to be better correlated with healing of the lesions.[5,6] However, measurement of blood pressure in the digital arteries requires the use of appropriate equipment,[6] which is not always available in the majority of health services, whereas the sphygmomanometer needed to calculate ABI is available in almost all vascular services.[1]

Ankle brachial indexes lower than 0.5 are generally associated with ischemia and are an indication for vascular assessment, since patients with intermittent claudication generally have an ABI ranging from 0.5 to 0.8, and ABI values ≤ 0.3 are associated with resting pain.[7] However, despite the fact that ABI is an easily executed and low cost test for health care, there are few studies differentiating the ABI values of diabetic and non-diabetic patients with critical ischemia in the literature.

The objective of this study is to determine whether there are differences between the ABI values observed in diabetic and non-diabetic patients with critical limb ischemia due to infrainguinal peripheral arterial occlusive disease (PAOD).

METHODS

This retrospective study was conducted at the Vascular Surgery Service at the Complexo Hospitalar Universitário Professor Edgard Santos, belonging to the Universidade Federal de Bahia (UFBA) in Brazil. Data were collected from archived patient records, clinical follow-up charts and arteriographic reports on patients who had been admitted between December 2006 and December 2011. The study was approved by the Research Ethics Committee at the Complexo Hospitalar Universitário Professor Edgard Santos.

The sample comprised 140 patients admitted for treatment of infrainguinal critical limb ischemia due to PAOD of atherosclerotic etiology, with normal femoral pulses on physical examination and for whom arteriography reports confirming diagnosis were available in the hospital archives. Only cases for which there was a record of the ABI values assessed by one of the departmental vascular surgeons using dorsalis pedis and posterior tibial arteries for lower limbs were included in the sample. Measurements for calculation of the ABI were taken with the cuff placed in the standard positions, above the elbow fold for upper limbs and immediately above the ankle for lower limbs, with the patient in a supine position. The tip of the transducer of the portable Doppler ultrasound unit was positioned at the projection of the brachial artery and of the dorsalis pedis and posterior tibial arteries and then the cuff of the sphygmomanometer was inflated until the sound of blood flow was no longer audible and then deflated until blood flow was first heard once more, providing maximum systolic pressure.[1] Patients were excluded from the study if they had been admitted for acute ischemia or for ischemic disease of non-atherosclerotic etiology, if they did not exhibit critical limb ischemia on admission or if they had aortoiliac PAOD.

All patient data were recorded on the service's standard clinical follow-up charts. A dedicated form was designed for collection of data from patient records and follow-up charts. Patients were divided into two groups, diabetics and non-diabetics, with the objective of conducting a comparative analysis of mean ABI values calculated using both dorsalis pedis and posterior tibial arteries for both groups. Patients were considered to be diabetics if they had a prior diagnosis of the disease and were being treated for it. The same criterion was used to classify patients with systemic arterial hypertension. Additionally, both groups were analyzed in terms of the Rutherford Classification[1] of the lower limb with critical ischemia[1] and presence or absence of falsely elevated ABI (> 1.15).

Patients with falsely elevated ABI, defined as ABI > 1.15, were excluded from the comparative analysis of mean ABIs values. We compared mean ABI values for diabetic and non-diabetic patients after stratification by three Rutherford Classification categories (4, 5 and 6).[1] The maximum ABI value considered normal, set at

1.15, was based on a population study available in the international literature which found that 1.15 was the highest mean ABI among people with and without PAOD and that the majority of the sample had an ABI ranging from 0.9 to 1.1.[8] Another study involving more than 13,000 people found that 1.15 was the median ABI among people without PAOD.[9] On this basis, we considered an ABI > 1.15 for a person with critical ischemia to be falsely elevated.

Data were tabulated on Microsoft Excel® and analyzed using Epi-info, version 3.3.2, released in February 2005. We used the chi-square test ($\chi 2$) to test for associations between DM and occurrence of falsely elevated ABI (a qualitative variable). Mean ABI for dorsalis pedis and posterior tibial arteries (quantitative variables) were compared between the two groups using analysis of variance (ANOVA), both for each group as a whole and for each group of patients stratified using Rutherford's Classification. A significance level of 5% ($p < 0.05$) was chosen as the cutoff for rejection of the null hypothesis, i.e. the hypothesis that there was no statistical difference between the groups in terms of the variables studied.

RESULTS

The entire sample comprised 140 patients, 60% of whom were diabetic, 76% hypertensive and 62% smokers. Ninety-eight (70%) had occlusive disease involving the femoropopliteal territory, with absent popliteal pulses on physical examination, and the remaining 42 patients (30%) had infrapatellar disease, with normal popliteal pulses. Mean age was 69.6 years. With regard to Rutherford's Classification,[1] 77% of limbs were classified as category 5, 17% as category 6 and 6% as category 4. The characteristics of the sample are shown in Table 1.

Table 1. Characteristics of the 140 patients with diagnoses of critical limb ischemia due to peripheral arterial occlusive disease (PAOD).

Characteristics of the sample (140 patients)		n (%)
Sex	Male	69 (49%)
	Female	71 (51%)
Mean age		69.6 years
Diabetes mellitus		84 (60%)
Systemic arterial hypertension		106 (76%)
Ankle-Brachial Index > 1.15		10 (7%)
Current smoking		87 (62%)
PAOD level	Femoropopliteal	98 (70%)
	Infrapatellar	42 (30%)
Rutherford's Classification	Category 4	08 (6%)
	Category 5	108 (77%)
	Category 6	24 (17%)

Nine diabetic patients (11%) and one (01) non-diabetic patient (2%) had ABI values greater than 1.15 ($p = 0.02$) and were excluded. After exclusion of the 10 patients with ABI > 1.15, all the remaining 130 patients in the sample were stratified by Rutherford's Classification. Mean ABI measured at the posterior tibial artery for the 130 patient with CLI was 0.26 ± 0.05 for patients in Rutherford category 4; 0.30 ± 0.08 for category 5; and 0.15 ± 0.04 for category 6. Mean ABI measured at the dorsalis pedis artery was 0.37 ± 0.06 for category 4; 0.27 ± 0.08 for category 5; and 0.31 ± 0.1 for category 6.

Comparative analysis of mean ABI values calculated for the dorsalis pedis and posterior tibial arteries for both groups of patients with critical ischemia (diabetic and non-diabetic) revealed that mean ABI for the posterior tibial artery was 0.26 ± 0.07 for diabetics and 0.28 ± 0.08 for non-diabetic patients ($p = 0.6$). Mean ABI for the dorsalis pedis artery was 0.32 ± 0.07 for diabetic patients and 0.23 ± 0.08 for non-diabetic patients ($p = 0.06$).

Comparison of diabetic patients with non-diabetic patients stratified by the three Rutherford classification categories (4, 5 and 6) only detected a significant difference between patients in category 6, for whom mean ABI values for the dorsalis pedis artery were higher for diabetic patients (0.44 ± 0.09) than non-diabetic patients (0.16 ± 0.08) ($p = 0.03$). Tables 2 and 3 show the results of the comparative analyses of mean ABI values for diabetic and non-diabetic patients calculated for the dorsalis pedis and posterior tibial arteries and stratified by the three Rutherford CLI classification categories.

DISCUSSION

According to the literature, calcification of the arterial tunica media is more prevalent among diabetics,[4,5] which often leads to discussions of the

Table 2. Comparative analyses of mean dorsalis pedis artery Ankle-Brachial Index (ABI) of diabetic and non-diabetic patients with critical limb ischemia, stratified by Rutherford Classification (n = 130).

Rutherford Classification	Mean Ankle-Brachial Index	p
Category 4		
Diabetic	0.50 ± 0.01	0.2
Non-diabetic	0.29 ± 0.07	
Category 5		
Diabetic	0.29 ± 0.07	0.4
Non-diabetic	0.24 ± 0.08	
Category 6		
Diabetic	0.44 ± 0.09	**0.03**
Non-diabetic	0.16 ± 0.08	

Table 3. Comparative analyses of mean posterior tibial artery Ankle-Brachial Index (ABI) of diabetic and non-diabetic patients with critical limb ischemia stratified by Rutherford Classification (n = 130).

Rutherford Classification de	Mean Ankle-Brachial Index	p
Category 4		
Diabetic	0.26 ± 0.06	0.9
Non-diabetic	0.25 ± 0.05	
Category 5		
Diabetic	0.29 ± 0.07	0.7
Non-diabetic	0.31 ± 0.09	
Category 6		
Diabetic	0.11 ± 0.03	0.4
Non-diabetic	0.19 ± 0.06	

applicability of the ABI for diagnosis of PAOD cases in these patients and assessment of their severity. The majority of studies of the prevalence of PAOD and ABI in diabetic and non-diabetic patients do not specify the values found in relation to cases of critical limb ischemia.[10-12] A study of the prevalence of peripheral arterial disease that assessed 2,375 people aged ≥ 40 years found that 4.5% of the non-diabetic patients and 9.5% of the diabetics had ABI ≤ 0.9,[10] the majority of whom were asymptomatic. Among diabetic patients, Thavitharam et al. found an overall mean ABI of 1.03 and detected a difference between those with PAOD (mean of 0.81) and those without PAOD (mean of 1.05).[11] Jirkovská et al.[12] reported on around 300 diabetic patients screened for risk of ulceration and stated that the mean ABI of patients with ulcers was 0.82 ± 0.42, while for those without ulcers it was 0.92 ± 0.26.

In Brazil, Makdisse et al.[13] reported a 36.4% prevalence of PAOD, diagnosed using a cutoff of ABI ≤ 0.9, in elderly subjects over 75, the majority of whom (64.2%) had some type of abnormal pulse finding and 34.7% of whom reported pain or discomfort in lower limbs.Another study, with 201 chronic renal failure patients found a 14% prevalence of PAOD diagnosed on the basis of ABI.[14] A study conducted in a university hospital with 248 patients diagnosed with PAOD found that 79 (32%) exhibited an ABI < 0.5, compatible with severe ischemia, and reported a mean ABI of 0.57 for symptomatic patients and 0.7 for asymptomatic patients.[15]

However, the majority of studies do not highlight differences between diabetic and non-diabetic patients diagnosed with critical ischemia by providing a break-down of their ABI values. In this study we compared diabetic and non-diabetic patients with critical ischemia caused by PAOD and, after exclusion of patients with falsely elevated ABI, we did not detect differences in mean ABI for the majority of patients. The prevalence of falsely elevated ABI (> 1.15) among our patients with advanced ischemia was 10%. The only patient in our sample who had excessively high ABI but did not have diabetes had chronic renal failure, which is also a disease that is linked with medial arterial calcification.

The great majority of patients in both groups had ABI values below the limits of normality, which does not only confirm peripheral vascular disease, but also indicates advanced disease, with mean ABI below 0.5. The majority of our patients already had gangrene and tissue loss, confirming the severity of their ischemic states and explaining the low mean ABIs observed in both groups.

Some arteriographic studies have detected differences between diabetics and non-diabetics, reporting that diabetics are more likely to have atherosclerotic disease below the knee.[16,17] However, histological studies show that atherosclerotic lesions of the lower limbs appear to have indistinguishable morphology and distribution in both groups.[4,18] Our study did not find differences between diabetic patients and non-diabetic patients in mean ABI at the posterior tibial artery in any of the Rutherford's Classification categories.

For dorsalis pedis artery ABI there were only difference between category 6 patients, i.e. patients with extensive tissue loss, and diabetic patients had a significantly higher mean ABI, which is probably the result of medial arterial calcification of the dorsalis pedis artery in this patients. During the 1960s, Strandness et al.[19] found that diabetics exhibited greater involvement of the posterior tibial, anterior tibial and fibular arteries than non-diabetic patients, but when they studied amputated lower limbs from both groups they found that little more than half of them had a patent dorsalis pedis artery. Histological studies have found similarities in the pattern of atherosclerotic disease in diabetic and non-diabetic patients.[4,20-22] We believe that since there is a similar pattern of atherosclerotic disease, but medial arterial calcification is more prevalent among diabetics, this was probably the cause of the difference in mean ABI among the category 6 patients with advanced ischemia. It should be stressed that the mean ABI values among these diabetics in category 6 were neither normal nor falsely elevated. The ABI values among diabetics in category 6 of the Rutherford Classification were still, on average, below 0.5, despite being statistically higher than the values observed among the non-diabetics.

Our study has the limitations inherent to a retrospective study. Notwithstanding, it offers a detailed analysis of the behavior of ABI values in diabetic and non-diabetic patients with severe critical limb ischemia (CLI), reporting the parameters observed in these patients. We very often see the claim that ABI is not a reliable method in diabetics. Our study shows that a small percentage of diabetic patients with CLI have a falsely elevated ABI and that in the majority of these patients with CLI ABI reflects the advanced arterial obstruction in leg arteries. Further studies are needed to evaluate the correlation between ABI values and prognosis in the cases of critical limb ischemia.

CONCLUSIONS

In our study, diabetic patients with critical limb ischemia had a higher prevalence of falsely elevated ABI. In general, excluding these patients with a falsely elevated ABI, diabetics and non-diabetics with CLI were not different in terms of mean ABI measured using the dorsalis pedis and posterior tibial arteries. However, when stratified by degree of ischemia, it was observed that diabetics in category 6 of the Rutherford Classification had higher mean ABI for the dorsalis pedis artery than non-diabetics in the same category.

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