Determination of the Ankle-brachial Index in Type 2 Diabetic Patients with an Automatic Oscillometric Device

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Abstract: An altered ankle-brachial index (ABI) is an indicator of peripheral arterial disease (PAD). Usually the measurement of the systolic pressure in both brachial arteries and pedal pulses is performed with a continuous-wave Doppler ultrasound. Recently an oscillometric automated device is available to measure ABI. This instrument is a simple to use, fast and accurate method suitable for common use in clinical practice. 701 patients with type 2 diabetes who attended consecutively in office were studied by 24 General Practitioners (GPs). 74 patients had an abnormal ABI (≤ 0.90), 240 a borderline ABI (0-90-0.99) and 7 patients ABI ≥ 1.40. All these patients received a Doppler ultrasound examination and 117 had an asymptomatic PAD. GPs reported that the device was easy to use and that it can be an useful instrument of early diagnosis of PAD in daily practice.

Keywords: Peripheral Arterial Disease, Ankle-brachial Index, Automatic Oscillometric Device, Type 2 Diabetes

1. Introduction

Peripheral arterial disease (PAD) is an atherosclerotic process leading to the reduction of the diameter of the major distal arteries in the aortic arch. A progression of stenosis results in a reduction of arterial flow and claudication, which is the most common and visible clinical symptom. Only 10% of patients with PAD show typical claudication; 50% of patients may suffer from an atypical pain in the legs and 40% of patients are asymptomatic [1]. The most important risk factors for PAD include diabetes, smoking, hypertension, age, hypercholesterolemia and chronic renal failure [2]. Smoking and diabetes are associated with a higher relative risk of PAD in the lower limbs. The Italian *2018 Standards for the Treatment of Diabetes Mellitus* recommend the measurement of the ankle-brachial pressure index (Ankle Brachial Index, ABI) for all patients over the age of 40 with type 2 diabetes and those diagnosed with diabetes over 20 years ago [3]. Furthermore, the *American Diabetes Association* recommends the measurement of ABI in all diabetic patients who are over 50 years old and/or who have been diagnosed with diabetes

more than 10 years ago or who were smokers [4].

Ankle-brachial pressure index. The ABI is the ratio between arterial blood pressure at the ankle and the arm.

It is an efficient and low cost method for establishing a diagnosis of PAD. The classical measurement methodology involves the use of two blood pressure cuffs, one on the ankle and the other on the arm. Once the cuff is inflated with air and slowly deflated, a pulse wave is recorded at the ankle using a Doppler probe and systolic pressure is measured at the foot's dorsal or posterior tibial artery. The same process is repeated for the arm by detecting the pulse wave and measuring the systolic blood pressure of the brachial artery. It possesses a high specificity (98%) and sensitivity (90%) [5]. The ratio between the two values is the ankle-brachial index. The interpretation of the results is shown in Table 1 [6].

Table 1. Interpretation of ABI values.

Ankle-brachial index (ABI)	Interpretation
≤ 0.90	Peripheral arterial disease
0.91-0.99	Borderline
1.00-1.39	Normal
≥ 1.40	Artery non compressible

The greatest limitations of the ABI measurement in daily practice is the time it takes to measure, having the suitable equipment and the ability to use it [7, 8]. An easy to use device that can be automated and which does not require particular specialist skills can simplify ABI detection, anticipate and increase the diagnosis of PAD in groups of the population that are at risk. The automatic oscillometric measurement of blood pressure is now widely used, accurate and easy to use [6]. This process, compared with the classic method, which involves the use of Doppler sonography, is practically superimposable and a strong correlation between the two methods has been demonstrated in various studies [6, 9-11].

2. Aim of the Study

The aim of the study is to evaluate the use of an automatic oscillometric device for the measurement of the ABI as part of good clinical practice that provides this assessment in diabetic patients.

3. Methods

Twenty-four GPs trained using this device, participated in this study and were invited to measure the ABI of the first 30 diabetic patients who would present themselves at the clinic for any reason. Each GP was provided with an iHealth CardioLab® - ABI Wireless device (Figure 1) which is composed of two auto-inflating cuffs that are synchronized and connected wirelessly to an Apple iPad with an *ad hoc* application. The purpose of this investigation was explained to the patient and, having consented, the patient was invited to lie on the examination bed. First, the pulse waves of the femoral, posterior tibial and dorsal arteries were recorded. Once both limbs were measured, the lowest ABI value was recorded. The medical record was then checked to see if an arterial Doppler ultrasound of the lower limbs was already required and, if necessary, could be claimed as normal good clinical practice after the medical examination.

Figure 1. iHealth Cardiolab® – ABI Wireless device.

4. Results

706 patients with type 2 diabetes were examined (386 males and 320 females), 5 of which did not have clinical or complete instrumental data and therefore were excluded from the analysis. 28 of 706 patients had already been diagnosed with PAD in their medical records, confirmed by an arterial Doppler ultrasound. Almost half of the patients had a normal ABI value, while more than one third of the patients had a borderline value. An abnormal ABI value (≤ 0.90) was observed in 106 patients (15.2%) and a value ≥ 1.40 in other 7 patients (1%) (Figure 2 and Table 2).
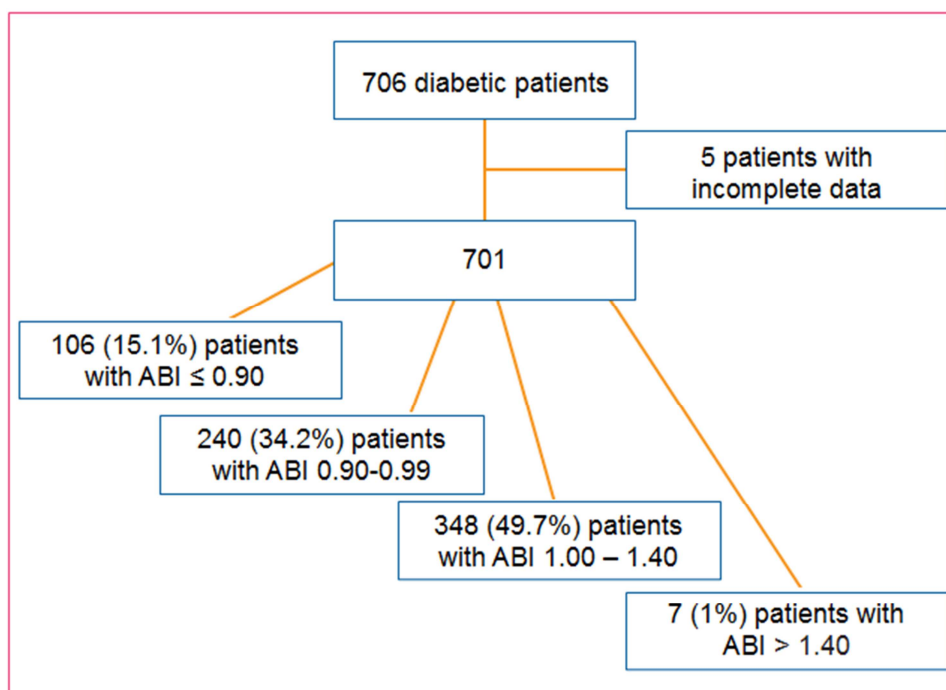

Figure 2. Consecutively examined type 2 diabetic patients (706) with respective ABI values.

Table 2. *Breakdown of patients by ABI values, changes in arterial pulses and pathological arterial doppler ultrasound.*

	ABI ≤ 0.90		ABI 0.90-0.99	ABI 1.00-1.39	ABI ≥ 1.40
Patients n	106		240	348	7
	28 already known with PAD	74			
Change in arterial pulse n. (%)		52 (70.2%)	84 (35%)	0	0
Patients with pathological arterial Doppler ultrasound n. (%)	Repeated for 17 as it was dated over a year ago	56 (75.6%)	55 (22.9%)	Not performed	6 (85.7%)

The arterial pulses recorded by doctors were altered in about 70% of cases where patients had an ABI ≤ 0.90 and in 35% of cases where patients had borderline ABI values (0.90 to 0.99) while pulse alterations were not reported in the remaining group of patients.

Three quarters of patients (75.5%) with an ABI ≤ 0.90, that did not know to have PAD, had an arterial Doppler ultrasound in the lower limbs that proved pathological while the percentage of those who had a borderline value of ABI was approximately 22.9% and 85.7% for those with an ABI of ≥ 1.40.

The data gathered in this study also demonstrates that the duration of diabetes is directly proportional to the increase in risk of PAD as shown in Table 3. The decrease in patients who were first diagnosed with diabetes over 21 years ago is probably due to the high mortality that this cohort has suffered due to major cardiovascular events.

Table 3. *Patients with ABI ≤ 0.90 in relation to the number of years since first diagnosis of diabetes (in five year periods).*

DIABETES DURATION (years)	Number of patients	ABI (average)	IC (95%)
0-5	3	0.87	0.84-0.89
6-10	12	0.84	0.80-0.87
11-15	25	0.79	0.73-0.85
16-20	22	0.74	0.67-0.80
21-25	24	0.76	0.69-0.83
26-30	16	0.78	0.72-0.84
≥ 31	4	0.83	0.77-0.88

5. Discussion

The data collected is a snapshot of normal clinical practice in which the measurement of the ABI with this oscillometric device was performed on more than 700 patients, who attended consecutively at GPs' practices that participated in the study. There was no significant selections or enlistment bias as patients involved were those who had gone to their family doctor's office for repeat prescriptions, for prescription monitoring or for the assessment of investigations of any kind that had been performed or for other reasons not related to diabetes, also. The systematic use of ABI (once a year) can help to determine a significant proportion of patients with asymptomatic PAD in the pre-symptomatic phase (75% of patients with pathological ABI [≤ 0.90] and nearly 23% of diabetic patients with borderline ABI [0.90-0.99] then had an abnormal arterial Doppler ultrasound). The use of this device is completely compatible with daily activities, it requires the same amount of time as for the measurement of blood pressure and it allows the detection of PAD in a percentage of diabetic patients who

otherwise would remain undiagnosed. The systematic use of this instrument would even avoid an over-demand for arterial Doppler ultrasound exams, reducing the cost for the National Health Service, waiting lists and inconvenience to patients.

The prevalence of PAD increases also with rising duration of diabetes [12] and the detection of pre-symptomatic PAD allows the physician to implement stricter control of the patient and use a more intensive therapy to improve the metabolic control, as PAD is a progressive disease and the risk of amputation after 5 years is estimated at 1-4% [13]. A pathological ABI value is an independent factor of future cardiovascular events [14]. An ABI value of <0.90 increases the relative risk of cardiovascular events and all-cause mortality by two to four times [15].

A systematic review examined all studies that had given ABI data at baseline and traced acute coronary disease, strokes and all-cause mortality in patients who had not any cardio- or cerebrovascular events [5]. A low ABI value has a predictive value of 92.7% for coronary artery disease [15]. After 5 years, 20% of patients with a PAD have a non-fatal heart attack while 15-30% die (three-quarters of these from cardiovascular deaths) [16].

6. Conclusions

The systematic use of the oscillometric device (iHealth CardioLab®) for determining ABI has enabled early diagnosis of PAD in more than 17% of cases (117 patients out of 673). In 20% of these patients, the pulse recording was normal. If the data prevalence of PAD in this cohort of patients was 4% (20/701) after using this device, it increased to over 17%, confirming that in type 2 diabetes the prevalence data appears to be significantly underestimated. Its use for patients with known PAD allows the replacement of an outdated arterial Doppler ultrasound that has not been recently rechecked. It can be considered an extraordinary preventive instrument against cardiovascular complications. Associating the oscillometric ABI values with the number of peripheral arterial pulses may also help reduce the number of false negatives and increase the diagnostic sensitivity of the test. For all these reasons, the ABI measurement with this easy to use, reliable and reproducible device can become a method of PAD screening in the daily routine of GPs.

Conflict of Interest

all the participants of the study. The devices are part of the educational tools that the researcher use for the vocational training programme.

Physicians participating in the study: Doriano Battigelli, Luciano Caraceni, Giulio Corgatelli, Gaetano D'Ambrosio, Antonino Di Guardo, Laura Federici, Alessandro Filippi, Gabriella Gentile, Giovanni Giardina, Saffi Ettore Giustini, Piero Grilli, Marco Martinetti, Carlo Fedele Marulli, Antonio Metrucci, Giorgio Carlo Monti, Giulio Nati, Italo Paolini, Gabriella Salladini, Lanfranco Sanna, Gabriele Scattolari, Aurelio Sessa, Paola Tagliabue, Raffaele Tota, Vincenzo Verrone.

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